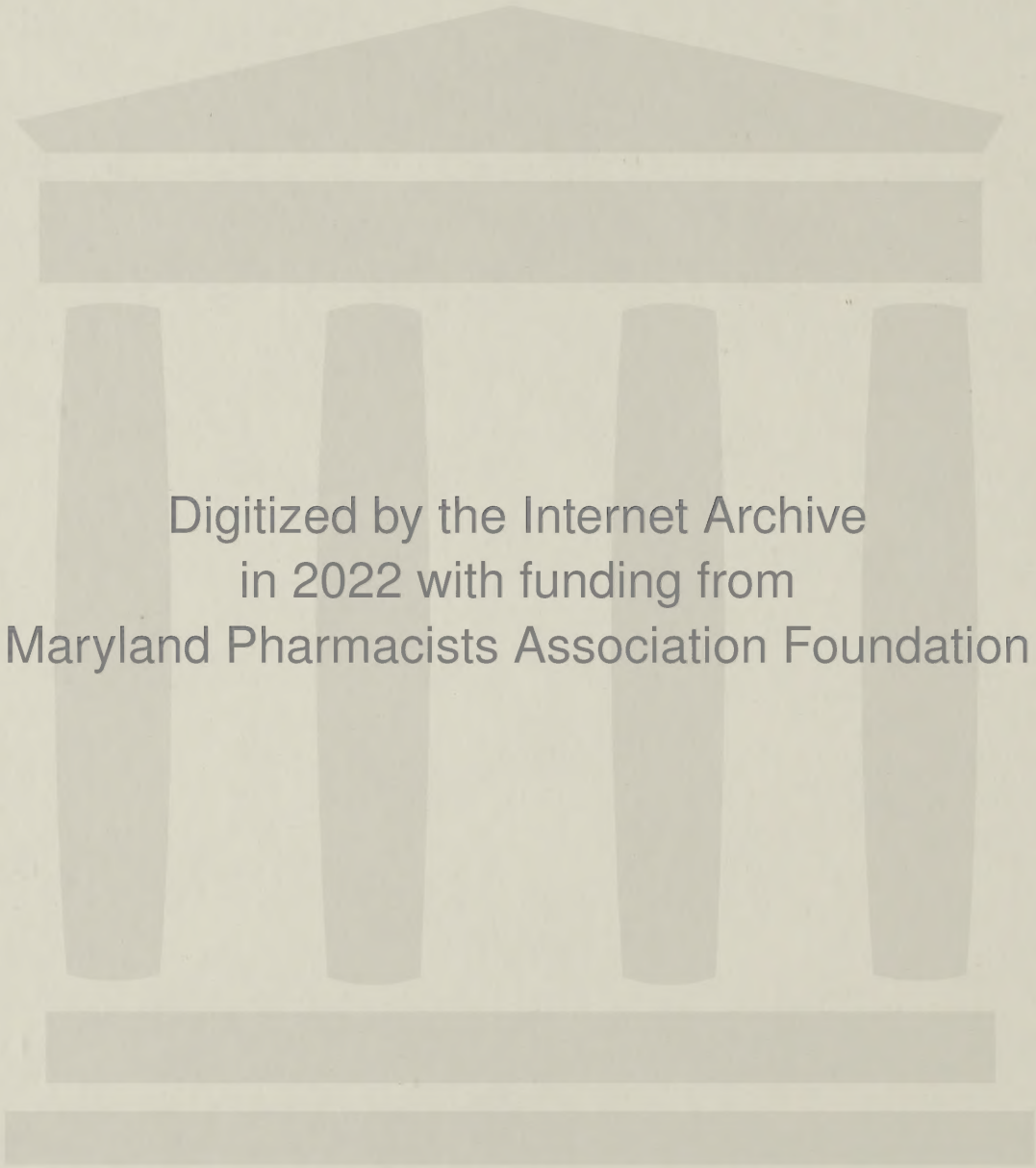

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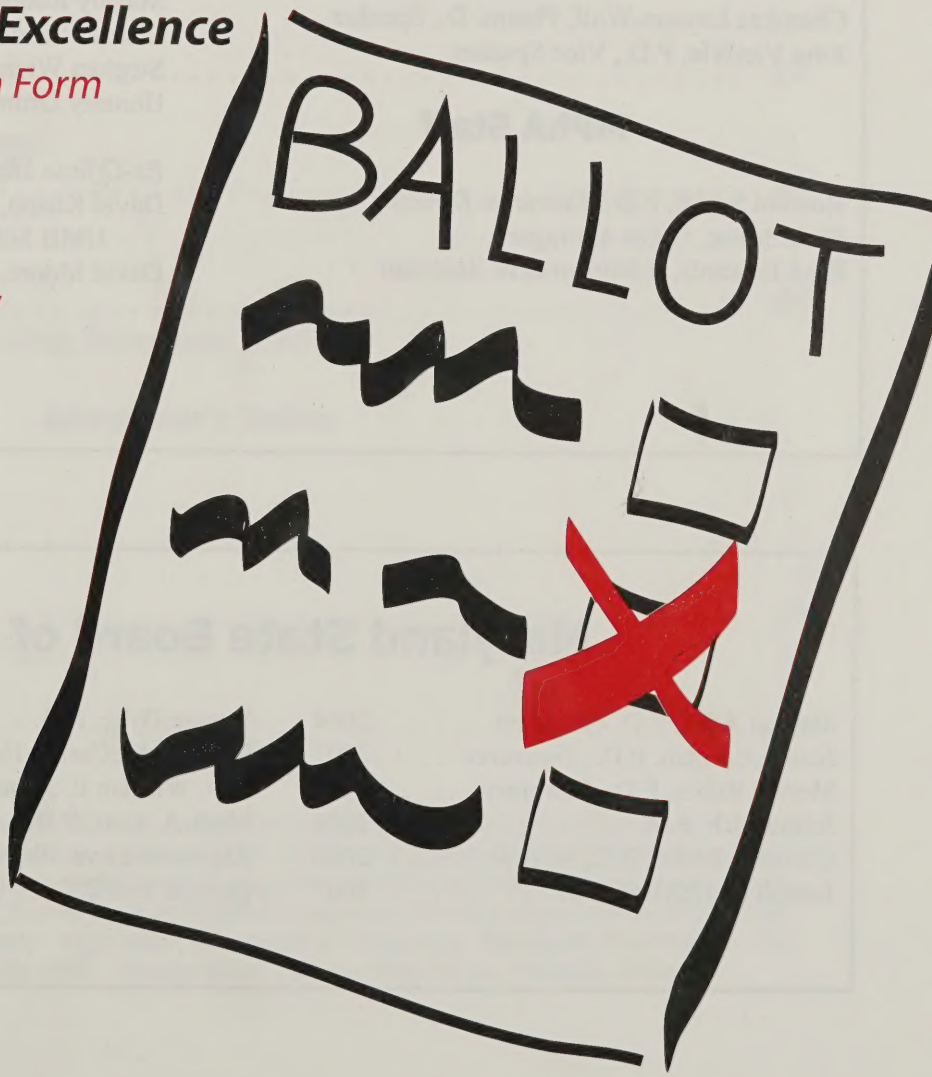
MARYLAND
Pharmacist
VOLUME 80 NO. 1

2004 Maryland Leadership Elections
Statements of the Candidates and Official Ballot

Recognizing Pharmacy Excellence
MPhA 2004 Awards Nomination Form

Continuing Education
Patient Counseling: "West Nile Virus Infections: A Primer"



MARYLAND PHARMACISTS ASSOCIATION
JAN / FEB / MAR 2004

Maryland Pharmacists Association

650 W. Lombard Street
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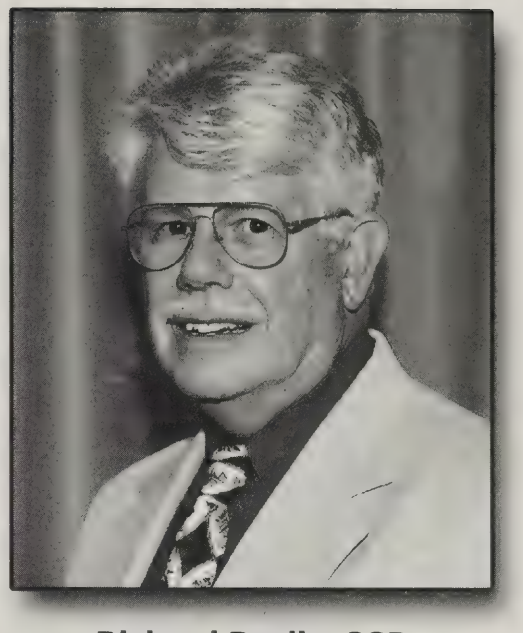
President's Commentary



Richard Baylis, CGP
President

I hope everybody had a very pleasant holiday season. I wish all our friends and members a Happy and Prosperous New Year!

Our association moves on into 2004 with many projects yet to be completed and a multitude of challenges facing us.

The on-going building renovations have been stymied by lack of funds. The pledges, so far, have been adequate to pay the work that has been completed, but future construction plans are in abeyance due to lagging payment of those pledged and new subscriptions by those not yet pledged. I have challenged our Fund Raising and Building/Museum Committees to actively remedy this situation.

Does our association have a strategic plan? No. Therefore, Cynthia Boyle, Chairperson of the Strategic Planning Committee has started to address this problem. She and her committee—Matthew Shimoda, Honesty Drumgoole, Magaly Rodriguez de Bittner, Ernie Testerman are working toward a Board of Trustee's retreat to work on such a plan.

Financially, the Executive Committee, under the able guidance of Phil Cogan, Treasurer, has submitted a balanced budget to the BOT that does not draw so much on our reserves for the first time in many years. Good work. Now let's keep up this momentum for future years.

The Drug Therapy Management Task Force, under Magaly Rodriguez de Bittner's guidance has formally asked the Board of Pharmacy to expeditiously move ahead with appointing the Protocol Oversight Committee so the law can be implemented as soon as possible.

Speaking of Magaly, the Association wishes to congratulate her on receipt of two very great honors accorded her in the last month. One is a special recognition award presented at the Annual Meeting of NCPIE and the second is the appointment as Assistant Dean of Students at the School of Pharmacy. We are very proud of you Magaly and pledge you our wholehearted support.

On the political front, we have three major items to address. One is the Medicaid Preferred Drug List. Second is our Pharmacists Immunization Authority Legislation to be introduced in the legislature in 2004. And third, the newly passed Medicare Reform Legislation passed by Congress in December 2003.

The Medicaid Preferred Dug List went into effect in November and is being added to every few weeks as the formulary committee reviews the drug categories. The listed has been posted for all to see on MPhA's web site. Updates are issued as the list is enlarged or edited.

The immunization initiative at the state legislature will require careful shepherding, but we are very hopeful as to its outcome. Please support the Maryland Pharmacy Coalition's Legislative day on February 19th by attending and making our case to our delegates and senators.

The Medicare Reform Act will not go into

effect until 2006, but next year discount drug cards may be purchased by Medicare recipients to obtain medications from their pharmacies. We need to keep a close eye on this issue as the proposed discount cards appear to be questionable in their effectiveness to lower medication costs to seniors and will we again be the one bearing the brunt of reduced reimbursement by the administrating PBM's.

So here's the challenge to our members and those non-members reading this:

1. We need your continued financial support both by membership fees, new members and expanded participation in pledges to the Foundation for the Building/Museum and Scholarships.

2. We need your active participation in all of our activities: attendance at the Mid-Year; the Maryland Pharmacy Coalition's Legislative Day February 19th; the Annual Meeting in June, and serving on committees— whatever your interests are.

3. We need your active feedback, either critical or praiseworthy. Feel free to e-mail the association office, mpha@starpower.net, write a letter to the editor, or calling Executive Director Howard Schiff at 410-727-0746 or by calling me 410-439-3527, or e-mail rbaylis@cablespeed.com.

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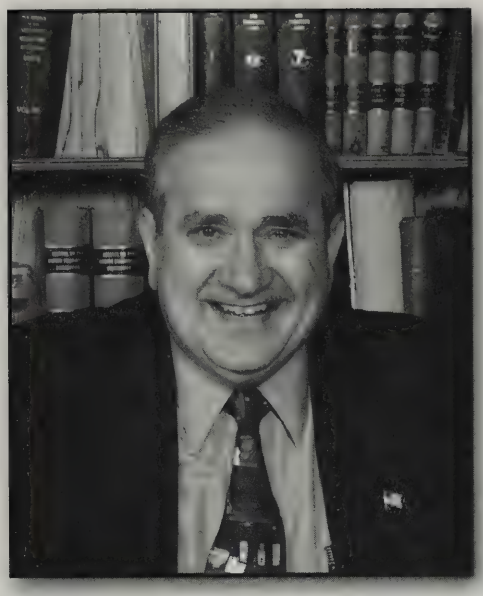

Howard Schiff
Executive Director

Depending on what facet of pharmacy your interests lie, you are either upset or reasonably happy with the Medicare bill.

Community pharmacists, with a vested interest in either their own pharmacy or in a managerial position with a chain, see a discount card now and coverage in 2006 for the last major group that had no insurance coverage. PBM provided services have reduced margins to what has been described as "vapor thin" levels. Couple those margins with competition from Canada, on-line pharmacies and mail order, all of whom have an advantage over community from the sales practices of manufacturers, and you can see why they're angry. Talk to any of us in community, however, and you'll find the realization that something must be done for seniors, but that it's grossly unfair for community pharmacy to bear the brunt of the discounts. Access to pharmacy services may be severely curtailed if that happens.

Meanwhile, those pharmacists who are involved, or hope to be involved in patient care, see federal recognition of pharmacy's role in drug therapy management as the first step toward payment for services. Pharmacy focus and education advocates have been striving for this goal for years. They point out that pharmacy is mentioned 400 times in the bill, not only in the provision of medications but also in access, choice of provider and standard drug card.

The old saying, "the devil will be in the details," applies here. Much of the bill enactment is left to regulations not yet promulgated. The skeptics point out that the big moneyed interests had a role in shaping the bill and will be there for the regulations. There will be some, namely PBMs, who will try to shortcut pharmacist face to face meetings with patients for their own ends.

Universal health care, health care for all, or health care for the uninsured, whatever you choose to call it, is also on the horizon and appears to have gained much support from those both on the right and left of the political spectrum. Challenges are not new to pharmacy. The truth of the matter is that Medicare reform and, possibly some sort of universal health care, is here and we will adjust to it and live with it.

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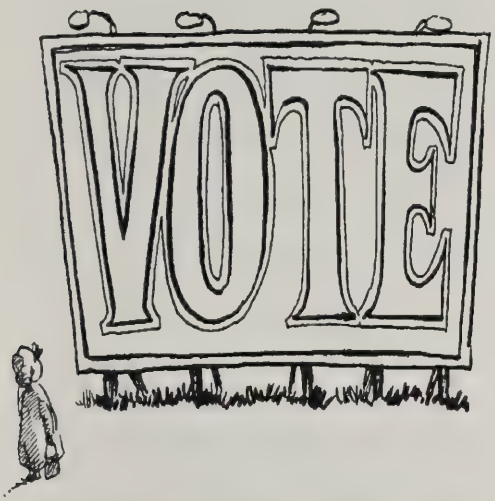
STATEMENTS OF THE CANDIDATES



Ginger Apyar
Second Vice President
Duquesne University School of Pharmacy, Community Practice-Happy Harry's, Inc.

We have much to celebrate as members of the Maryland Pharmacists Association and also much work to do for our profession. That is why I am running for the office of Second Vice-President. I am currently practicing as a community pharmacist on the Eastern Shore. I moved over from "retail", as it was referred to when I graduated, after a number of years to become a managed-care pharmacist working for a large PBM. I have found from my career moves that whatever descriptive term is placed in front of the word pharmacist, we all share the same pride in our profession and also the same challenges. I have also found from my career choices that the dynamics of pharmacy practice are ever evolving. As pharmacists, we must be on the forefront of change in order to direct this forward motion. If not, the profession of pharmacy will be shaped by those not schooled in our science. We all have seen the results of change created by non-pharmacists. We continue to struggle with the complexity of these changes; pharmacist's work-load and stress has increased, quality of life has decreased, insurance issues intrude on our time for patient care. If elected Second Vice-President, I would work with the membership to help assure that pharmacists are defining our profession.

I am currently serving as a member of the Board of Trustees. Previously, I have served as Vice-Speaker, Speaker of the House of Delegates, Membership Chairman and Convention Chairman. I regularly attend the Board of Trustees meetings and participate in Legislative Day. I am a preceptor for the University of Maryland School of Pharmacy Experiential Learning Program. I am an active member of the Eastern Shore Pharmaceutical Society and the American Pharmacists Association. I am in the Maryland Pharmacist Volunteer Corp for emergency response to bio-terrorism and a Board of Pharmacy liaison for the local health departments in 4 counties: Queen Anne, Kent, Talbot and Caroline.

What a proud history MPhA has of promoting excellence in pharmacy! It would be an honor and a privilege to serve as your Second Vice-President; to advance the expectations the members have for MPhA and the profession.

Phil Cogan
Treasurer
I have been a member of the Maryland Pharmacists Association for approximately 30 years. My allegiance to the Association has been demonstrated over that period in many ways. I have served in every elective office of the Association, and I have chaired many of its standing and ad hoc committees. Currently, I am the treasurer and wish to continue in that capacity.

I have made real progress in reshaping the Association's financial outlook. There is still much that can be done. We now have a tighter budget planning process. We have been able to separate the MPhA Foundation from the financial matters of the Association. I still would like to see greater emphasis on non-dues revenue and better conservation of the Association's financial assets.

I have an understanding of the issues facing the Association and take seriously the fiduciary responsibilities of the Treasurer. I wish to continue being a strong and vocal advocate for the membership regarding how the resources of the Association are spent and how the policies of the MPhA House of Delegates are implemented.

Neil Leikach
Trustee Seat # 1
When I received a phone call from MPhA about running for a trustee seat I ask myself, why me? Maybe I was asked to run because I have been a member since I graduated from Maryland in 1992, have gone to conventions and meetings and feel it is important to be part of an organization that helps me grow professionally. The growth of MPhA will only occur if the young members become active and help guide the group. I am the treasurer and past president of the University of Maryland School of Pharmacy Alumni Association, member of AZO and a lifetime member of NCPA. I will bring my background as an independent pharmacy owner to the board and will be honored to have this trustee seat. The voice of independent pharmacy has been brought back into the spotlight because of EPIC pharmacies and I feel the independent's needs have to be heard in MPhA.

Charles A. Sandler
Trustee Seat #1
I am a past president of the University of Maryland School of Pharmacy Alumni Association and have served on its executive board since 1970. I am a member and past president of AZO fraternity and have served on its executive board. I was a member of the executive board of BMPA until its merger with MPhA. I have been a trustee of the MPhA since 2000. I am also enrolled in the Pharm.D. program at the University of Maryland.

A common misconception about the profession of Pharmacy is that the pharmacist is only responsible for dispensing prescriptions. As any practicing pharmacist is aware, the job of a pharmacist is multifaceted and obviously extends beyond filling prescriptions. As pharmacists, we must council patients about medications and potential interactions, as well as spend time communicating with insurance companies regarding formularies and product selections. Thus, the job that we perform obviously entails more then filling prescriptions, and therefore we should not be compensated by a fixed per prescription fee that fails to adequately cover the services that we render. Instead we must strive to have insurance companies recognize our more comprehensive role in patient care and have them compensate us accordingly.

Mary E. Kremzner
Trustee Seat #2
LCDR United States Public Health Service (PHS); Team Leader, Division of Drug Information
Office of Training and Communica-tion; Center for Drug Evaluation and Research (CDER); Food and Drug Administration (FDA)

Mary Kremzner is a Team Leader in the FDA's Division of Drug Information. Her work involves strategic planning, and overseeing day-to-day operations in support of the division mission. Dr. Kremzner has a variety of responsibilities such as writing for FDA's web site, creating CE presentations; she was instrumental in the development a 2-year Pharmaceutical Fellowship with industry and academia and is responsible for creating the student program in the division. She acts as a mentor to new PHS officers, students, and new employees. She regularly hosts visiting representatives of foreign governments and presents overviews on CDER's role in drug development.

Dr. Kremzner is a thought leader, with strong technical skills and understanding of complex systems. She has a unique ability to identify areas of need, bring people together and accomplish set goals. Her focus as a trustee would be two-fold: give back to the profession that has brought her so much satisfaction and success and take the MPhA to a new level of membership and participation.

Dr. Kremzner has worked continuously in retail pharmacy for 15 years and continues to maintain her skills as a practicing pharmacist by working part-time for Watermont pharmacy. She received her degrees from the University of Maryland, B.S. in pharmacy in 1987 and her Pharm. D. in 1998.

Magaly Rodriguez de Bittner
Trustee Seat #2
University Puerto Rico School of Pharmacy, University of Maryland School of Pharmacy, Graduation Year: B.S. - 1979; Pharm.D. - 1983
Practice: University/Community Pharmacy/Ambulatory Care Clinic
Employer: UMB School of Pharmacy and VA Hospital

I would like to the MPhA membership for allowing me the opportunity to serve as MPhA trustee for the past three years. As my term comes to an end, I reflect on the things our Association has accomplished and the job that is ahead of us.

This past year the Collaborative Practice law passed in our state and regulations have been approved. As the Chair of the MPhA Drug Therapy Management Task Force, I continue to work to make patient care the focus of pharmacy practice and to develop training programs and protocols that will assist pharmacists in our state implement collaborative practice. I will continue to find ways to move the profession of pharmacy forward.

Patient care must be the focus of pharmacy practice. It must be an integral part of our pharmacy functions, which include dispensing. We must continue to develop effective practice models that demonstrate our impact in patient outcomes and the financial feasibility of such programs. Collaborative practice can be an effective way to achieve these goals. As pharmacists, we need to work together to reach our professional goals.

Changes in health care, particularly the recently approved Medicare law, are bringing dramatic changes to our profession. We must define our future. If we do not act now, someone else (other health care professionals, regulatory organizations, government agencies, or insurance companies) will define it for us. Pharmacists' working conditions, payment for cognitive services, collaborative practice and technology are just a few of the issues that our Association must address. I want to continue to be a trustee and to help MPhA develop solutions for these complex issues as an innovative force that moves each one of us to act.

I bring to MPhA enthusiasm, experience, leadership and commitment to excellence in pharmacy practice. It would be an honor to continue my service as MPhA trustee. Thank you for your support. I look forward to serving you for three more years!

Joe Marrocco
Trustee Seat # 3
Duquesne University, Practice Site - Giant Pharmacy 1973
Pharmacists today, in many spheres of practice, find themselves inundated with many issues, while striving to adhere to the "safety and reliability" code that they deem essential to their patients and fellow healthcare colleagues. Corporate America might choose to call this "multi-tasking," yet when this might involve superfluous issues, are we being asked to compromise the innate goals that were highly instrumental in our choosing of pharmacy as our professional careers. Has "bottom Line" economics invaded our spheres of practice? Certainly! To a large degree, if we are honest with ourselves.

Your Maryland Pharmacists Association offers its members and actually, all pharmacist colleagues, a highly committed group of practitioners and professionals that encompass many spheres and disciplines, from community, to hospital, to long term care, to independent owners, consultants, educators and faculty administrators that strive to promulgate pharmacy's mission of practicing the "best patient care" in all areas, without compromise to safety.

I offer to you, our MPhA membership, an "open ear" to your concerns and an avenue for your issues. Having served presently and prior, as an elected trustee, vice president, and speaker of the house, I have, and will continue a near perfect meeting attendance and voice for our mutual concerns, and the vitality of our practice setting and patient care. I sincerely request your consideration of my candidacy for your MPhA trustee. Thank you.

Steven Samson
Trustee Seat #3
I am applying for the position of trustee of the Maryland Pharmacists Association. I am a 1991 graduate of the University of Maryland School of Pharmacy and have practiced in the retail setting for 12 years at Giant Pharmacy. I began as a staff pharmacist. After 3 years, I was promoted to pharmacy manager at several different locations. Because of my excellent managerial qualities, I was promoted to pharmacy manager at the busiest prescription Giant in Maryland, a position I held until 2002. In 1995-96, I was elected the Merchandising Pharmacist of the year by Drug Topics magazine. During this time, I helped to oversee the day

to day operation of the first in the nation chain pharmacy diabetes management center, which was started by Dr. Magaly Rodriguez deBittner.

I have been on several committees for Giant. The most recent one dealt with work flow management. I also represented Giant Pharmacy as a member of a Maryland Board of Pharmacy committee addressing pharmacy related errors. My present position is staff night pharmacist at the same store I had previously managed. I took this position to afford me more free time for family which includes my wife Tina (also a pharmacist) and 3 children. In this position, I work one week on and one week off, giving me more time to devote to my family and also allow more time for other interests. I believe that I have the ability, experience, and desire to represent the working pharmacist and all the issues we face.

Scott S. Kuperman
Trustee Seat # 4
Maryland Practice Experience: Independent Community Pharmacy, Chain Community Pharmacy, Pharmacy Education.
I have been a MPhA member since 1988 and worked over 15 years in community practice, the first ten of which were as a pharmacy manager for an independent. Here I became well acquainted with the difficulties and rewards inherent in this setting. I have seen our profession constantly assailed on all sides by third party issues as we attempt to provide vital clinical services to our patients. From this experience it has become clear to me that pharmacists must be pro-active in dealing with such situations. I believe that becoming active in MPhA is one of the best ways to accomplish this goal.

I have been a preceptor for UMAB for over a decade. I became a preceptor because of my belief in "giving back". I try to teach my students the importance of being the best practitioners they can be and how their efforts can benefit the profession and society as a whole.

For the past 5 years I have been a compounding pharmacist for NeighborCare Pharmacies, acting as the company's compounding information resource as well. From this dual role, I have learned how approaching situations creatively results in finding novel solutions to difficult problems, as well as the importance of networking and teamwork for the benefit of the greater good.

With your support, I would like to devote my energy and experience to supporting those programs which will benefit all of us and our profession. I would be honored if you will entrust this duty to me. Thank you for your consideration.

Carol Stevenson
Trustee Seat # 4
University of Kansas, 1970, B.S., University of Maryland, 2002, Pharm.D., Practice: Community Pharmacy Manager Senior Retirement Community
Employer: NeighborCare
As a Maryland pharmacist for over 30 years, I have had the opportunity of working in both hospital and community pharmacy, and the privilege of working overseas in the military setting. It is indeed a wonderful profession we practice, and what opportunities we have to provide valuable healthcare.

The University of Maryland gave me the chance to obtain a Pharm.D through the non-traditional program. What a challenge to grow professionally! I was able to connect with other Maryland pharmacists as real colleagues and to see first hand what a great pharmacy school we have in Maryland.

I work in a retirement community practice and see the impact we can have on the elderly. They truly depend on our valuable expertise. They have great concerns about the changes in healthcare, particularly in drug benefits. We need to be able to step up to the challenges and show that we can impact patient outcomes. I hope we can work to be recognized as providers of healthcare, not just dispensers of medicine.

One of the best parts of working in pharmacy has been the opportunity to be a preceptor. I have had students in institutional and community practice and was chosen as Preceptor of the Year in 2001. These future pharmacists are bright, motivated, and hard working young people, and we must nurture them and help them understand the value of our professional organization.

MPhA needs the support of all pharmacists to uphold high standards, to recruit the best and brightest future pharmacists, and to help us define the future of our profession. I would be an honor to serve as trustee of MPhA.

2004 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

Second Vice President

☐ Ginger Apyar

Treasurer

☐ Phil Cogan

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

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☐ Neil Leikach
☐ Charles Sandler

Trustee Seat # 2

☐ Mary Kremzner
☐ Magaly Rodriguez de Bittner

Trustee Seat # 3

☐ Joe Marrocco
☐ Steve Samson

Trustee Seat # 4

☐ Scott Kuperman
☐ Carol Stevenson

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, ***received by Friday, April 23, 2004***. For questions, please call MPhA at 800-833-7587.

Only official ballots from the "Maryland Pharmacist" journal will be accepted—no photocopies.

Fold

2004 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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toxtidbits

provided by the maryland poison center

Batteries Included...

Many of the toys and electronics that will be given as gifts this holiday season are powered by small disc batters. These batteries are often unintentionally swallowed by small children, and some-times adults. Although the majority of these batteries pass through the gastrointestinal tract without incident, occasionally they will lodge in the esophagus and cause injury.

The most commonly ingested disc batteries are 11.6 mm in diameter or smaller. Other standard battery diameters are 15.6 mm and 23.0 mm. The chemical systems that are in these batteries include mercuric oxide, silver oxide, manganese dioxide, zinc and lithium. An alkaline electrolyte is also present and is usually 26 to 45% sodium hydroxide or potassium hydroxide. Lodged batteries may cause local tissue within the battery and cause tissue necrosis. In addition, electrolysis of sodium chloride generates sodium hydroxide with subsequent tissue injury even in the absence of actual cell leakage. Another contributing factor might be an electrical current that passes through the tissue. A lodged battery may exert constant mechanical force against the tissue resulting in pressure necrosis. Although, mercury-containing batteries often leak, no cases of clinical mercury toxicity have been seen.

X-ray localization is recommended in all cases of suspected button battery ingestion to confirm the diagnosis and location of the battery. Batteries located in the esophagus required immediate endoscopic removal. Esophageal damage can occur with 6 hours of ingestion. If the battery has passed beyond the esophagus, the patient may be sent home and instructed to inspect the stools to confirm the passage of the battery. The patient should return for a repeat X-ray in 4-7 days if the battery is not seen in the stools, or if the patient develops symptoms such as vomiting, tarry or bloody stools, fever, abdominal pain, or decreased appetite. In some cases, it might take up to 14 days for the battery to pass. Endoscopic or surgical removal may also be considered in cases where the battery stops progressing through e GI tract. A word of caution: it is sometimes impossible to distinguish between batteries and coins on the x-ray. This has led to devastating results form delayed removal of the battery.

DID YOU KNOW THAT...Hearing aids are a common source of batteries ingested by small children?

A study of 2,382 cases of battery ingestions reported to a national registry showed that 46.6% of batteries were obtained from heearing aids. In 32.8% of these cases, the battery was removed from the child's own hearing aid. Occasionally, adults swallow disc batteris as a aresult of putting them in their mouths while changing batteries, or when mistaken for their pills.

Recognizing Pharmacy Excellence
The 2004 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 122nd Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Friday, April 9, 2004.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years.

- **Wyeth Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. Any MPhA member pharmacist who has not already received this award.

- **Elan Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care.

Maryland Pharmacists Association Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than ***Friday, April 9, 2004***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ **Pharmacist Mutual Distinguished Young Pharmacist Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice
_____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Seidman Distinguished Achievement Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice
_____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Elan Innovative Practice Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice
_____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Wyeth Bowl of Hygeia**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice
_____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **MPhA Honorary President**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice
_____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

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Baltimore, MD 21201-1572

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Maryland Pharmacists Association
650 W. Lombard Street
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Pharmacy Profiles: Building Connections

Vincent "Vinny" Ippolito, Entrepreneur

By Cynthia J. Boyle

With this article continues a series of profiles of Maryland Pharmacists Association (MPhA) members, who are making contributions in their practices and communities, overcoming challenges, and pursuing distinctive interests. I hope you will continue to enjoy getting acquainted with some of these people in this journal, and I encourage you to suggest names for future interviews by emailing ***cboyle@rx.umaryland.edu*** *or calling 410-706-1495.*

Vincent Ippolito and Student Kristine Rapan

I met Vincent "Vinny" Ippolito at the recent MPhA Mid-Year Meeting on the campus of the University of Maryland, Baltimore. I picked a table for lunch based upon two criteria: people I did not know and a sunny location. As it turned out, I had joined the "Southern Maryland" table where I got to talk with Vinny and his colleagues. Having practiced pharmacy in Lexington Park for five years, I felt right at home.

Vinny's accent gave him away; he is a Maryland transplant too. He graduated in 1982 from Arnold and Marie Schwartz College of Pharmacy and Health Sciences at Long Island University. Although he took the New York licensing examination, he never practiced there. He has not really connected with the University of Maryland School of Pharmacy and finds many of his friends to be graduates of other schools.

CB: Were you prepared for pharmacy?
VI: I don't think so. I first started in pharmacy working for Peoples Drug, which was a good company. At that time, on a busy day we would process 60 prescriptions. So much has changed since then. I think the biggest issues for pharmacists are third party payments, liability, and increased volume and workload.

CB: How do you stay current?
VI: Jokingly, I would say I call Leo (Mallard). Actually, I attend association meetings and read journals. Continuing education is the best thing that has happened to pharmacy.

CB: How did you become a member of MPhA?
VI: Peoples Drug converted to Dart Drug, and Ron Sanford was Director of Pharmacy. He mentioned MPhA to me, and he was very active in the association.

CB: Do you feel a part of MPhA, since you are in Southern Maryland?
VI: I feel a little removed, since I am outside Baltimore. Actually I am closer to Washington, D.C. I have always maintained my MPhA membership. I used to be a member of APhA, but that membership has lapsed.

CB: Why do you renew your membership in MPhA?
VI: I think all pharmacists should be members of their state pharmacy association. You can stay current and learn what other people are trying in their practices. There are a lot of benefits to that, and with similar interests, we have the same legislative concerns.

CB: What is your practice like now?
VI: It is about to change. I hope to open my own pharmacy by the end of the month, or early next month. It is called Northgate Pharmacy Inc. in Waldorf on St. Charles Parkway. My dad is a retired teacher and will serve as my partner and secretary-treasurer. As is said, "Failure is not an option." I will be part of Care Drug, which is a franchise operation that started as a buying group. It is small, with over forty pharmacies in Maryland, Virginia, and the District of Columbia. I value that they provide support for opening a pharmacy and involvement with the members. I have met President Jerry Sarota. I look forward to being in control of my practice; my hours will be 9-7 Monday through Friday, and 9-2 on Saturday.

CB: How did you decide upon a location?
VI: I signed a lease back in December because of a great opportunity. Village Drugs in Waldorf closed. Those files were sold to a pharmacy two miles down the road. I found a location one-half mile from the former location of Village Drugs, on the way to the location which bought the files.

CB: What will be the role of technicians in your new practice?
VI: I have hired one technician who worked for Village Drugs for 17 years. She comes with excellent references. I also hired a former clerk and two part-time workers for deliveries and clerical assistance. One is the 16 year-old aunt of my daughter. I think technicians are essential, and it would be a good thing for them to be registered with the Board of Pharmacy.

CB: What is best for you outside your new business?
VI: My daughter Ashley, who is 12 years old and in the seventh grade. She is starting to consider her career but is not ready to commit. She has worked with me, and I hope to involve her in the business too.

I asked Vinny's colleagues about his best qualities. They agreed that he is dependable, fun to be around, and entertaining. I was told that Vinny's associate Wally Szot, in response to a comment that a life is not well-lived if it does not leave a ripple, said that "In the ocean of life, Vinny is a tidal wave!"

Rx AND THE LAW

By Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

PHARMACISTS: PUBLIC HEALTH CRUSADERS

Reports of a particularly nasty flu season, coupled with an apparent shortage of vaccine product make it a challenge to get flu shots, especially late in the season. However, for people living in states that allow pharmacists to administer vaccines, access to flu shots may be easier. There are 37 states that allow pharmacists to administer vaccines.[1] If you practice pharmacy in one of these states, consider becoming certified to administer vaccines. If you practice in a state that does not allow pharmacists to administer vaccines, work with your state association to urge your state to change its laws to allow pharmacists to perform this important role in protecting public health.

Why should pharmacists become involved in the administration of vaccines? One important reason is access. Convenient locations and business hours make pharmacies an attractive option for people who want a flu shot but do not want to take the time and effort involved with a doctor appointment. In addition, pharmacists are in an excellent position to identify people in high-risk groups who have the greatest need for immunization. Finally, because pharmacists are a trusted source of health information, they are in a unique position to educate patients about the benefits and risks associated with immunization.

Pharmacists can make a tremendous impact on the rate of vaccination simply by educating patients and directing those with the need for immunization to a source for receiving immunization. Although the pharmacist's role as educator and facilitator is crucial to increasing rates of vaccination, pharmacists can have an even greater impact on vaccination rates by actually administering vaccines. This is because the pharmacist ensures that the patient actually receives the vaccine. A recent study showed that the administration of vaccines by pharmacists has increased rates of vaccination among several segments of the population.[2] In 1999, Iowa pharmacists administered approximately 30,000 doses of influenza vaccine.[3] That number represents 30,000 people who may not have received a flu shot if they had to go to the doctor or health department to do so. And the numbers of vaccinations performed by pharmacists are growing.

How does one go about getting involved in administering vaccines? Check with your state pharmacy association or state board about the requirements you need to meet in your state. Many states require pharmacists to become certified, something I personally achieved recently when I completed a certificate program. It was an intense combination of home study, classroom, and hands-on learning. I learned a great deal about immunology and vaccine-preventable diseases, as well as vaccine schedules, administration techniques, storage requirements, and tips for billing Medicare for influenza and pneumococcal vaccine. I am confident that pharmacists who successfully complete this program are well qualified to administer vaccines.

Many pharmacists are concerned about the possibility of additional liability exposure associated with the administration of vaccines. This is a legitimate concern, but if certification is obtained, protocols are followed, and storage and record-keeping requirements are met, this is a manageable risk. Another consideration before you begin is professional liability coverage for vaccine administration. Check with your professional liability insurer to make certain you have coverage for this important activity.[4]

As health care professionals, we pharmacists all bear a certain degree of responsibility for the public health. Involvement in the administration of vaccines is a golden opportunity for pharmacists to assert our role in improving the health of the nation. By removing barriers to vaccine access, we offer our patients a tremendous service. I urge you to examine your current role in vaccination efforts and consider increasing your involvement in some concrete way.

© Karen E. Peterson, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

[1] http://www.immunize.org/laws/pharm.htm

[2] Grabenstein JD, Guess HA, Hartzema AG, et al. Effect of vaccination by community pharmacists among adult prescription recipients. *Med Care*. 2001;39:340-8.

[3] Figures reported to Iowa Pharmacy Association by pharmacies that administer vaccines.

[4] Pharmacists Mutual's professional liability policies specifically provide coverage for "drug administration, including immunization, where permitted by state law by you as a pharmacist."

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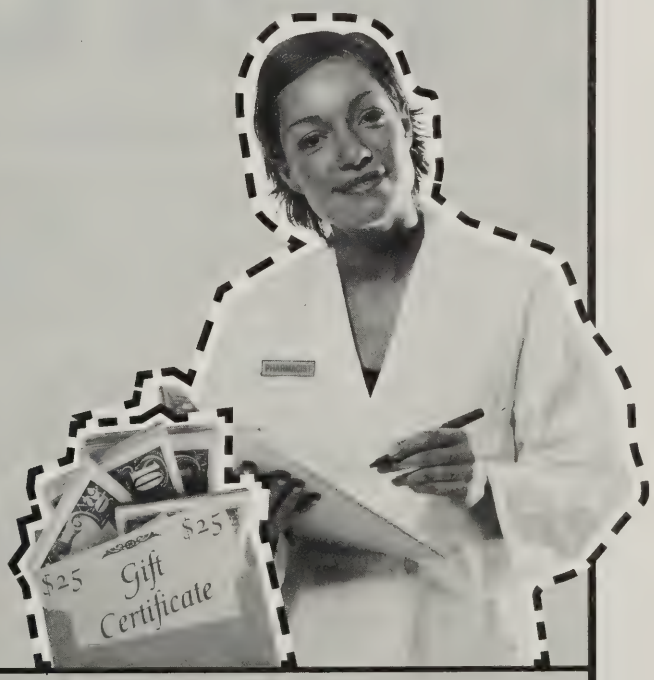

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Continuing Education for Pharmacists

Volume XXI, No. 6

Patient Counseling: West Nile Virus Infections: A Primer

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this lesson is to describe infections caused by the West Nile virus.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. recognize symptoms of infection caused by the West Nile virus;
2. select from a list the risk factors of the disease and the means of virus transmission;
3. exhibit knowledge of the pathophysiology, prognosis, prevention, and treatment of West Nile virus infections; and,
4. demonstrate an understanding of how to counsel patients on the West Nile virus.

This lesson is provided by an educational grant from

PHARMACIA

Gossel

Wuest

Background

Important vector-borne human pathogens have been introduced to North America due to world-wide travel and global commerce. These include dengue, yellow fever, malaria, HIV, and plague. More recently, the West Nile virus has been added to the list of pathogens that originated in one part of the world, but have now been introduced into another area thousands of miles away. It is not clear how the virus arrived in this hemisphere in 1999, but because it first appeared in a major international gateway port, New York City, it is believed that it was transmitted via travel or commerce. The virus' rapid spread westward across the U.S. over the past four years, and more recently into southern Canada and probably Mexico, has led health authorities to conclude that the West Nile virus is now firmly established in the Western hemisphere. Expansion is linked to the migratory patterns of birds and will likely continue. The virus is expected to reach the west coast of both the U.S. and Canada in the summer of 2003. Important features of the virus in North America are summarized in Table 1.

Epidemiology

Until 1999, the West Nile virus was confined to Africa, west and central Asia, the Middle East and Europe. It was first identified in 1937 in a febrile adult woman in Uganda. A few other human outbreaks were recorded later, predominantly associated with mild febrile illness in soldiers, children, and healthy adults in Africa. A flare-up in Israel during 1957 resulted in profound neurologic involvement and death. Since the mid-1990s, both the frequency and clinical severity of outbreaks involving hundreds of persons and inflicting severe neuro-

Table 1
Key Facts Concerning West Nile Virus in North America

- Infection is acquired by a bite from an infected mosquito; the geographic distribution of the infection is expanding in this hemisphere.
- One in five infected persons develops mild fever; one in 150 develops meningitis, encephalitis, or both.
- Advanced age is by far the greatest risk factor for severe neurologic disease, long-term morbidity, and death.
- Presence of West Nile virus-infected birds, onset of meningitis or encephalitis in late summer or early fall, and profound muscle weakness provide important diagnostic clues.
- There is an effective test for West Nile virus that detects the presence of antibodies in cerebrospinal fluid or serum; testing is available through state and local health departments.
- Rapid reporting of possible cases to health departments is essential to guide public health control efforts.

Source: *Annals of Internal Medicine* 2002; 137(3):173-179

logic sequelae have increased in several European countries.

While a major epidemic of West Nile virus infection has not yet been confirmed in the U.S., national surveillance has validated its virulence. Persons in this country who have contracted the virus and developed serious illness have suffered mostly from encephalitis and meningitis. Onset of illness for the most part has ranged from mid-July through early-December, peaking in late-August and early-September, in northern states. In southern states, transmission may occur year-round. It is not possible in this lesson to provide a detailed description of the latest statistics on the spread or infectivity of the West Nile virus because the data are constantly changing. However, by April 16, 2003, the Centers for Disease Control and Prevention (CDC) had verified 4156 human cases from 2002, resulting in 284 deaths. Up-to-date information may be obtained from CDC by visiting its website (www.cdc.gov) or the Food and Drug Administration's website (www.fda.gov).

Ecological Considerations

It is believed that the enzootic cycle (i.e., characteristics for a particular life-form) of the virus in North America is the same as in the Eastern Hemisphere and involves birds (reservoir hosts) and mosquitoes (vectors for transmission). After mosquitoes complete three aquatic stages (egg, larva, pupa), adult insects emerge in the spring. Viral amplification ensues in a bird-mosquito-bird cycle until later in the season when temperatures begin to fall and mosquitoes bite less frequently.

As mosquitoes feed on blood from a virus-infected bird, they become infected. The virus can then be transmitted in 10 to 14 days to another bird, human, or other animal that the mosquito bites. The virus replicates in its new host. Although humans and some animals may experience symptoms following infection with the virus, it is believed that these hosts usually do not develop sufficient blood levels of virus to infect subsequent mosquitoes that may bite later. Consequently, humans and animals such as horses are referred to as *incidental*, or dead-end hosts.

Unlike other infectious viruses such as HIV and hepatitis B and C which remain in the blood for long periods, West Nile virus is short-lived in the blood. Available evidence supports the contention that most infected persons develop antibodies against the virus within one to two weeks. These antibodies help protect the person against re-infection, except it is possible that immunity decreases in later years. Although the virus disappears, the antibodies may be detected in a person's blood for years, resulting in a positive blood antibody test. There is no indication that such a person is chronically infected.

The enzootic cycle can be modified by numerous environmental factors including weather or climate, host and vector predators, and host immune status. Ideal environmental conditions promote sufficient numbers of mosquitoes such that, as a result of their increasing numbers, by mid- to late-summer they pose a threat to humans. There is no evidence that the infection can be spread directly from person to person or from animals to humans. Additionally, there is no evidence to suggest that infection can be spread through casual contact such as touching or kissing a person with the virus.

By spring 2002, the virus had been identified in more than 40 North American mosquito species. This number will likely increase as the virus continues its spread into new habitats. Mosquitoes (primarily *Culex pipiens*, *C. restuans* and *C. quinquefasciatus*) are reported to be the most important vectors in the eastern U.S. at present. However, it is unclear which species, or even others, pose the greatest threat for transmission of the virus to humans.

There have been significant mortality rates reported among susceptible birds that have accompanied outbreaks in humans in Israel and the U.S. This has been most notable among American crows and other North American corvids (i.e., ravens, blue jays, and other crows). More than 130 species of birds are known to have been infected with West Nile virus. Most infected birds survive their initial encounter with the virus. This assures continued persistence of the virus from one season to the next.

Virology

The West Nile virus consists of a single-strand of RNA contained within a lipid envelope and belongs to the family Flaviviridae, genus *Flavivirus*. It is a member of the Japanese encephalitis virus serocomplex, a group of virus species of which several are important medically because they are associated with human encephalitis. To date, there have been very few genetic changes noted to occur in the virus found in the U.S. This offers optimism that a vaccine may soon be developed to immunize humans against outbreaks and antiviral medications identified to treat established infections.

Clinical Manifestations

It appears that the incubation period of West Nile virus ranges from three to 14 days. Many human infections do not present with marked clinical manifestations beyond mild illness with fever, headaches, body aches, and sometimes skin rash and swollen glands.

A survey of infected persons in the 1999 New York City epidemic revealed that only 20 percent of them developed fever, with approximately half of these visiting a physician for their illness. Little is known to-date concerning the full clinical spectrum of symptoms and signs associated with infection because surveillance efforts have concentrated on persons who had frank neurologic disease.

Reports from earlier outbreaks characterize the infection as a febrile illness with sudden onset often accompanied by a vague feeling of discomfort (malaise), loss of appetite (anorexia), nausea, vomiting, headache, eye pain, muscle pain (myalgia), rash, and swollen lymph glands (lymphadenopathy). These features usually persisted three to six days.

While victims of outbreaks of West Nile virus appear to have increased morbidity and mortality, profound, life-threatening neurologic disease is uncommon. In a survey conducted in Romania during a 1996 epidemic, meningitis or encephalitis resulted in only one patient in 140 to 320 persons infected. A similar survey among infected persons in the 1999 New York City outbreak reported one case in 150 infections.

Advanced age is reportedly the most significant risk factor for severe neurologic disease. The risk increases proportionally in persons 50 years of age and older. In the 1999 New York City outbreak, an analysis of attack rates concluded that the incidence of severe neurologic disease was 10 times higher in persons aged 50 to 59, compared with those 19 years of age or younger. The incidence was 43 times higher in persons 80 years of age or older.

Patients hospitalized with West Nile virus infection in the U.S. (1999), Romania (1996), and Israel (2000) developed life-threatening encephalitis – meningoencephalitis (inflammation of the spinal cord and brain) more frequently than meningitis alone (62, 60 and 58 percent, compared with 32, 40, and 16 percent, respectively). The majority (>90 percent) of seriously ill hospitalized patients experienced fever, weakness, gastrointestinal symptoms, headache, and altered mental status. A small number had skin rash described as an erythematous macular, papular, or morbilliform (i.e., resembling measles) eruption appearing on the neck, trunk, arms, or legs. Nearly one-half of the hospitalized patients in the U.S. experienced severe muscle weakness. Muscle weakness may be a deciding symptom to suggest infection by the West Nile virus, especially when it accompanies encephalitis. Close to 10 percent of patients in the New York City epidemic suffered flaccid muscle paralysis. Of those who develop encephalitis, fewer than than one out of 1000 will die.

Other, rare, neurologic sequelae included failure of muscular coordination (ataxia), extrapyramidal signs, cranial nerve abnormalities, optic neuritis, polyradiculitis (i.e., inflammation of the nerve roots), and seizures. Reports from early outbreaks occasionally described myocarditis, pancreatitis, and hepatitis. There is no documentation that a developing fetus is at risk due to its mother's infection with West Nile virus.

CDC stresses that initial diagnosis of West Nile virus is based on clinical suspicion rather than on objective data. Diagnosis may be strongly considered when adults ≥50 years of age develop encephalitis or meningitis during the summer or early fall that cannot otherwise be explained. The discovery of dead birds or identification of other human cases in the area should raise suspicion. Recent travel to a site known to harbor the virus raises a red flag.

The most efficient method to confirm a suspected diagnosis is detection of IgM antibodies to the virus in the serum or cerebrospinal fluid collected from the individual within eight days of illness. An IgM antibody capture enzyme-linked immunosorbent assay (MAC-ELISA) can quickly confirm the diagnosis. Identification of victims with acute West Nile virus infection offers significant public health benefits to the individual, as well as others in the vicinity, by alerting them to the possibility of spreading human infection and possible necessity for medical treatment.

Clinical Outcome

Fatality rates reported for hospitalized patients have ranged from 4 percent in Romania (1996) and 12 percent in New York City (1999), to 14 percent in Israel (2000). Severe muscle weakness, encephalitis and unconsciousness were other important considerations in predicting death due to infection.

Some reports hint that preexisting conditions, including diabetes mellitus or immunosuppression, may be risk factors for fatalities associated with patients with West Nile virus. In one investigation of West Nile infections in patients with cancer, those with malignancies of the blood experienced prolonged viremia and severe illness more commonly than individuals with other types of cancer.

Treatment

Treatment is currently supportive, involving hospitalization, intravenous fluids, respiratory support, and prevention of secondary infections such as pneumonia for patients with severe disease. As of early 2003, more than 300 drugs had been screened to treat the disease. Twelve were shown to have potential for additional testing in animals, according to the National Institute of Allergy and Infectious Disease.

A vaccine to protect people against West Nile virus was scheduled to begin human trials in early 2003. The vaccine joins components from two viruses: an approved yellow fever vaccine as the backbone with genes from the West Nile virus inserted within. Controlled clinical trials in the management of West Nile virus encephalitis have not yet been completed for these agents, or for other treatments, including corticosteroids, anticonvulsants, or osmotic agents.

Prevention

The FDA has alerted the nation's blood banks to screen potential donors and eliminate those who might be infected with the virus. Guidelines issued in October 2002 advise the blood industry to encourage all donors to report any illness

Table 2
Patient Advice for Avoiding Mosquito Bites to Lessen the Chance of Infection

- Apply an insect repellent containing DEET when outdoors.
- Wear long-sleeved clothing and long pants when possible in areas where mosquitoes are likely to be present. Treat clothing with DEET. If you spray clothing with DEET, there is no reason to apply it to your skin underneath.
- Do not spray repellents containing permethrin directly on exposed skin.
- Try to avoid outdoor areas where mosquitoes are found between dusk and dawn.
- Eliminate sources of standing water from around your home where mosquitoes lay their eggs. This includes flower pots, clogged rain gutters, swimming pool covers, discarded tires, buckets, barrels, and cans. Change water in bird baths at least once a week.
- Install screens to doorways and windows and ensure they are in good repair by checking them regularly, and making sure that other routes of mosquito access to buildings and living space are blocked.

suggestive of West Nile virus infection withing two weeks after donating blood.

For the immediate future, West Nile virus infection control will probably depend on two general strategies: (1) decrease the number of mosquitoes through local control actions, and (2) prevent mosquitoes from biting humans by use of mosquito repellents and barriers such as window screens, wearing long-sleeved clothing, reducing time outdoors particularly in the early evening, and generally avoiding locations that harbor high concentrations of mosquitoes. General advice for means to avoid mosquito bites is presented in Table 2.

Mosquitoes breed in wet areas, and *Culex* sp. favor those areas where there is decaying organic matter (e.g., leaves, grass clippings, animal waste). Only a thin layer of water is necessary and the water does not need to be left standing for long periods: some mosquito species can reproduce within a week.

Although, there is no evidence that the infection can be transmitted from handling live or dead infected birds, individuals should still take care when doing so. They should avoid bare-handed contact with any dead animal, and use gloves or double plastic bags to dispose of a carcass, or contact the local health department for guidance. CDC recommends that hunters use caution when processing game animals.

Mosquito Repellents. The most popular repellent, DEET (N,N-diethyl-meta-toluamide), is effective in concentrations of 10 to 50 percent. Higher concentrations (up to 100 percent) are available, but do not confer increased efficacy and their duration of action is only slightly greater. The American Academy of Pediatrics suggests that concentrations no higher than 10 percent be used on children.

Formulations are available as liquids, lotions, sprays, sticks, and impregnated materials (e.g., wristbands). The U.S. Environmental Protection Agency (EPA) estimates that every year, approximately one-third of the U.S. population is expected to use DEET products.

DEET may be applied directly to skin, pets, clothing, tents, bedrolls, and screens. It is safe when used as directed. Serious toxicity (i.e., degeneration of the brain: encephalopathy) has been limited to inappropriate (i.e., excessive or chronic) use in children. DEET repellents are not recommended for infants less than two years of age.

Permethrin is a pyrethroid (synthetic pyrethrin derivative) with repellent and insecticidal characteristics. These repellents can be applied to clothing, tent walls, mosquito nets, and other fabrics, but not directly to skin. Other repellents, such as citronella, are also available, but they have limited repellent activity.

The EPA offers specific recommendations for safe use of products containing DEET. These are provided in Table 3.

Table 3
Advice for Using DEET Products Safely

- Read and follow all directions and precautions on the product's label.
- Do not apply over cuts, wounds, or irritated skin.
- Do not apply to hands or near eyes and mouth of young children.
- Do not allow young children to apply this product.
- Use just enough repellent to cover exposed skin and/or clothing.
- Do not use under clothing.
- Avoid over-application of this product.
- After returning indoors, wash treated skin with soap and water.
- Wash treated clothing before wearing it again.
- Use of this product may cause skin reactions in rare cases. The following additional statements will appear on the labels of all aerosol and pump spray formulation labels:
  --Do not spray in enclosed areas.
  --To apply to face, spray on hands first and then rub on face. Do not spray directly onto the face.

Source: www.epa.gov/pesticides/factsheets/chemicals/deet.htm

Summary

Human illness from West Nile virus, even in areas where the virus has been reported, is rare. The majority of persons who have been bitten by an infected mosquito develop infection with little more than a fever. However, the West Nile virus can cause severe and sometimes fatal illness.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: West Nile Virus Infections: A Primer." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 6/15/06. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-03-006-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. The first identified case of West Nile virus infection was reported in:
   a. 1907.
   b. 1937.
   c. 1967.
   d. 1997.

2. Expansion of the West Nile virus in the Western hemisphere is linked most closely to the migratory patterns of:
   a. birds.
   b. butterflies.
   c. humans.
   d. mosquitoes.

3. Persons in this country who have contracted a West Nile virus infection and developed serious illness have suffered mostly from:
   a. agranulocytosis.
   b. convulsions.
   c. encephalitis.
   d. immunosuppression.

4. The cycle of ecological characteristics for a particular life-form such as the West Nile virus is referred to as:
   a. biologic.
   b. mutagenic.
   c. histologic.
   d. enzootic.

5. Which of the following statements about a West Nile virus infection is true?
   a. Infections can be spread directly from animals to humans.
   b. Antibodies are detected in the blood within one to two hours.
   c. Infections can be spread directly from person to person.
   d. The infection is short-lived in the blood.

6. The West Nile virus belongs to which of the following?
   a. Egyptovirus
   b. Flaviviridae
   c. Herpesvirus
   d. Rhinovirus

7. The most significant risk factor for severe neurological disease resulting from a West Nile virus infection is reported to be:
   a. advanced age.
   b. blood type.
   c. ethnic background.
   d. mental acuity.

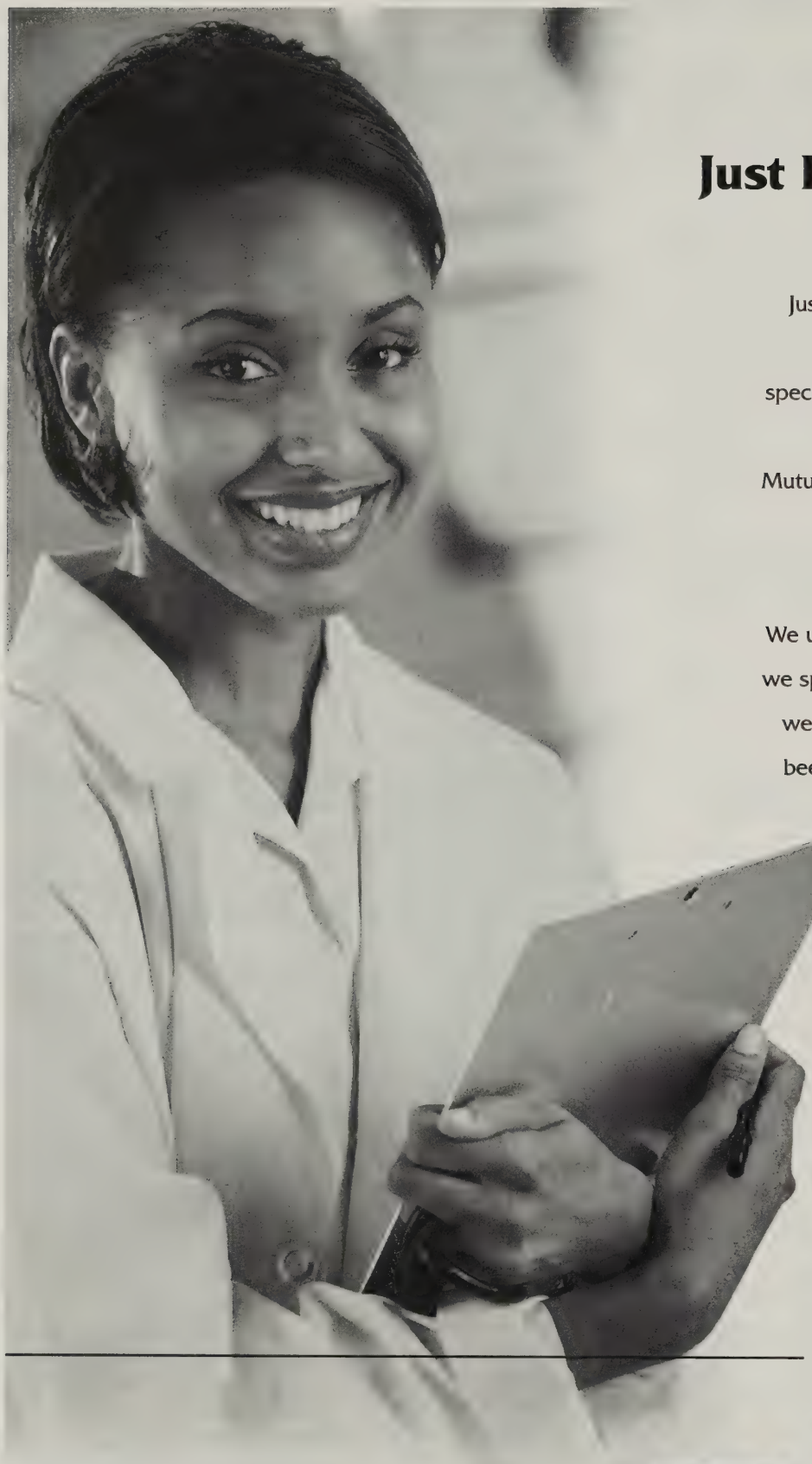
8. The most efficient method for confirming a suspected diagnosis of West Nile virus infection is detection of which of the following types of antibodies in the patient's blood?
   a. IgA
   b. IgG
   c. IgM
   d. IgR

9. All of the following are reported to be successful strategies for preventing mosquito bites EXCEPT:
   a. using mosquito repellents.
   b. reducing time outdoors in the early evening.
   c. wearing long-sleeved clothing when outdoors.
   d. taking thiamine tablets.

10. The insect repellent most likely to be effective for repelling mosquitoes is:
   a. citronella oil.
   b. diethyl-meta-toluamide.
   c. organophosphate.
   d. phenazopyridine.

Note: *Continuing Education Certificates are not processed out of the MPhA office. Therefore, for each reissued certificate there will be a $5 fee for members and nonmembers.*

CORRECTION: The corrrect ACPE number for Patient Couseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.



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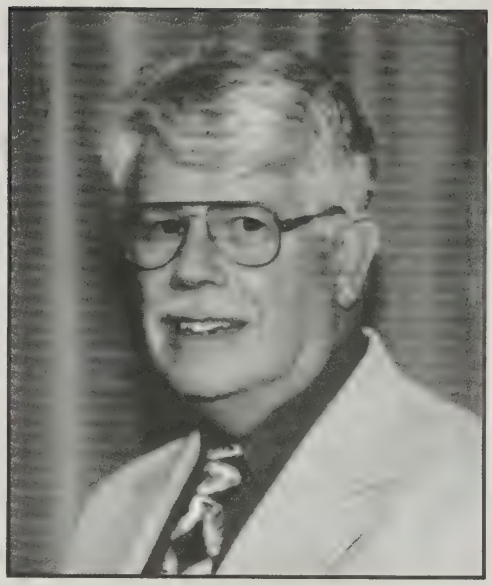
President's Farewell



Richard Baylis, CGP
President

This has been an exciting and eventful year for the Association and me. My plans for the term have been met and I am very proud of the cooperation and participation of the officers and members of MPhA in implementing them.

We had a wonderful annual meeting last June, in Ocean City. The educational programs were timely and well attended. The social times were as memorable as ever. AND, we made money which always helps the budget. This year, Ginger Apyar, Chair, and the members of the Convention Committee, have done an outstanding job in planning our Annual meeting and the Mid-year meeting. The Mid-year's programs were very well received by the attendees. And this year's Annual Meeting, is bigger and better than ever.

Budget wise our treasurer, Phil Cogan, produced a balanced budget which draws a minimal amount from our reserves. This was accomplished by having the Foundation/ Museum share the operating and administration costs of the association. This puts a greater emphasis on the fund raising efforts of the Foundation.

Our President-Elect, Cynthia Boyle and her committee put together a wonderful and fruitful strategic planning day for the Officers and Board of Trustees. Our association has needed to readdress our purposes and goals for a while, as we have not done this in several years.

The membership committee, chaired by Trustee, Dixie Leikach, has successfully promoted membership to more of our employed pharmacists and managers, thereby creating more steady income and representation among our fellow professionals within our organization.

Bart Regan and Phil Cogan, wearing another hat, have been actively participating on the Department of Health and Mental Hygiene Emergency Response Committee. We can be proud that Maryland is one of the few states that are actually meeting the federal goals for this important public health program.

Murhl Flowers, past- president, and David Moore, of MSHP, Co-chairs of the MPC Legislative Day Committee, produced a very successful day in Annapolis in February. We had the largest turnout ever. The issues addressed were well received by the Delegates and Senators we visited.

The B. Olive Cole Museum was appraised for insurance purposes. The appraisal saved us about $4000 a year in insurance costs. The next step is to catalogue and mark the items. Doug Campbell, Building and Museum Chair, will head this up. We have volunteers to act as guides when we open the museum to the public. The signs in front and the back of the Kelly Building have been replaced thanks to the generosity of Arnold Davidov.

Publicity has been the name of the game this past year. Howard and I have appeared on several TV spots and been interviewed by the newspapers and radio stations on many topics having to do with medications and healthcare. We are starting to make the media aware that we have something to offer the public when it comes to medication use. We now have access to a weekly radio show for seniors on WCBM. I serve of the programming committee for this program.

We broke out NCPIE's "Be MedWise" program at our Mid-year meeting. Magaly Rodriguez de Bittner, Trustee, started the program at a national press conference in Washington last year and presented the program to us in February.

Magaly is also our Chairperson of the Drug Therapy Management task force. She and her committee have been pushing the Maryland to move ahead on implementing the approved regulations. This is an issue we must continue to vigorously pursue as time is short to make the program work before the sunset provision sets in.

Now we move on to another year and a new president, Cynthia Boyle. The unresolved issues leftover from this past year need to be tidied up and the new challenges faced.

Medicare Drug Benefits will take much of our attention and time. This will also be tied to Medicaid Benefits as populations covered by either program are shuffled around by the government budget experts.

I wish to thank all the support and untiring devotion to duty of the Board of Trustees, Executive Director Howard Schiff, Office Manager Elsie Prince, and our office staff Nancy Ruskey and formerly Rosa Edwards.

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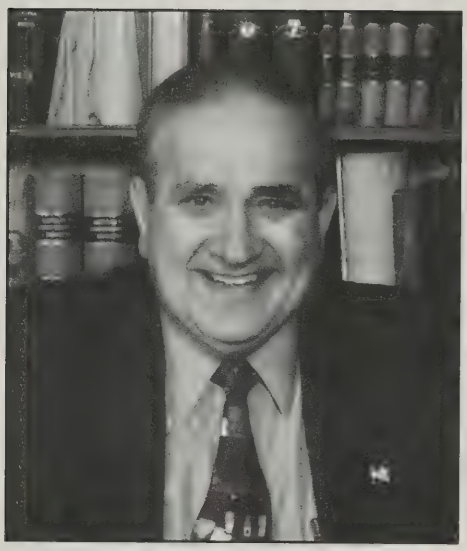

Howard Schiff
Executive Director

Optimism and Pessimism in Maryland Pharmacy

Optimist: The new Flu administration bill has passed both Houses of the Maryland General Assembly and the Governor has signed it. Maryland will join forty-one other states that allow injections. Great News!
Pessimist: The bill only covers flu; regulations have to be approved by the Board of Physicians and the Board of Nursing; it still doesn't cover medications usually self-administered or finger sticking for capillary blood tests.

Optimist: The new Medicare Discount Card will bring many more seniors into pharmacies. They will receive medications they've either neglected to take or obtained elsewhere. Pharmacists will be able to counsel more appropriately. Pharmacy Benefits Managers (PBMs) will pass on manufacturer discounts to make prescription drugs more affordable.

Pessimist: The new Medicare Drug Discount Card will enrich the PBMs and their mail order plans to which they will steer seniors. PBMs will continue to hide manufacturer rebates from payers and will continue to cut reimbursements to pharmacies. Seniors will come to the pharmacy with a pocket full of discount cards and will want the price from each on ten different Rxs. Margins will be cut so much, permit holders will be unable to afford the techs necessary to allow pharmacists to counsel.

Optimist: The FDA will toughen inspections of drugs shipped into the U.S. to limit counterfeit drugs. Prescriptions from Canada will cease to be a problem as cost for them and other industrialized countries will increase as American costs decrease. Manufactures will limit exports based on previous usage.
Pessimist: The FDA will relax importation rules under a mandate from Congress. Imports will triple or quadruple from the $1 billion of 2003. Access to pharmacies for acute illness medications will be limited by cutbacks on the number of pharmacies and shortening of hours and services of others. Congress is still looking for the bodies from citizens taking counterfeit drugs.

Optimist: The Maryland pharmacy tech bill is going to interim study so that a bill in 2005 will satisfy *all* parties.
Pessimist: The Maryland pharmacy tech bill is going to interim study so that a bill in 2005 will satisfy *no* parties.

Optimist: The Medicare Reform Act as written will go into effect in 2006 as scheduled.
Pessimist: The Medicare Reform Act as written will go into effect in 2006 as scheduled.

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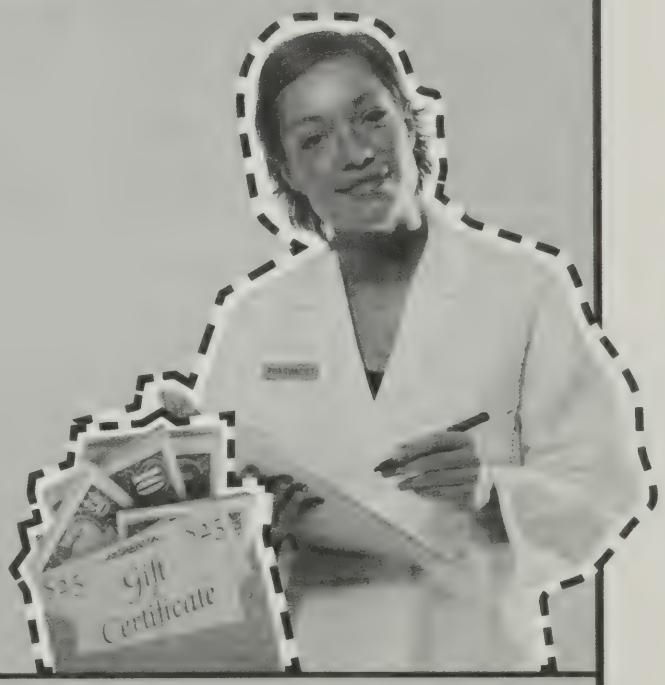

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The State of Maryland offers so much in the way of opportunity and natural beauty for our citizens. However, the positive attributes that make Maryland and the Baltimore/Washington metro region such an enjoyable place to live also provide more promising targets for terrorists. That's why I'm so proud of the more than 500 Maryland pharmacist volunteers who have been trained to help local health departments respond to bioterrorism. There is no higher calling than serving your own community, particularly as an expert volunteer.

As more is learned about the threats against us, we have a better understanding that many potential victims of attack commute to high-profile target areas and then return home to bucolic settings. These citizens may only later become aware that they were exposed to harmful toxins or biological weapons. In a time of crisis and biological attack, local health departments and pharmacist volunteers will be on the frontline and saving lives.

Despite our advances in preparedness, there is a definite need for additional pharmacist volunteers in rural areas of the state, including the Eastern Shore and Western and Southern Maryland. If you have not done so already, I encourage you to consider volunteering and helping to augment local health departments in a time of emergency.

Thank you for providing such a valuable service to your local communities.

Sincerely,

Wayne T. Gilchrest
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Rx AND THE LAW

By Don R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

"THE LEARNED INTERMEDIARY DOCTRINE"

A number of cases decided in the last couple of years have wrestled with the problem of a pharmacist's duty to warn patients of a drug's possible side effects. These cases have not had uniform results that would have been instructive for pharmacists. In fact, each case seems to confuse the issue even more. A recent case[1] tries again to deal with this thorny problem.

Judith Walls and her husband, Alan Adams, were being treated for scabies in 1986. The physician prescribed lindane for Mr. Adams, but prescribed a different, unnamed drug for Ms. Walls because she was pregnant. Later, Ms. Walls called her doctor to tell her that the treatment wasn't working. The physician instructed Ms. Walls to use her husband's prescription of lindane. A daughter was born in early 1987 and she suffers from numerous medical ailments allegedly caused by the use of lindane.

This case was filed against the manufacturer and the pharmacy in the United States District Court for the Northern District of Alabama. It is not clear from the case if the prescribing physician was sued. The United States District Court certified two questions to the Supreme Court of Alabama.[2]

1. Does a pharmacist have a duty to warn of foreseeable injuries from the use of prescription drugs that he/she is dispensing under Alabama law?
2. If yes, does the duty to provide adequate warnings extend to third parties whose injuries are reasonably foreseeable at the time of dispensing?

The Supreme Court of Alabama begins by examining the Learned Intermediary Doctrine. It discusses a number of cases from other state and Federal courts that extend this doctrine to pharmacists. The Learned Intermediary Doctrine is an exception to the general rule that a manufacturer must warn foreseeable ultimate users of dangers inherent in its

1 Walls v. Alpharma USPD, Inc., f/k/a Barre-National, Inc., et al., 2004 WL 406759, Supreme Court of Alabama, March 5, 2004.

2 Federal courts apply the law of the states where they sit. Federal courts may certify questions to the state supreme court on issues that have not been decided by the state's highest court. In essence, the Federal court says, "What would the law be if this question was presented to you in a case?"

products. However, for manufacturers of pharmaceuticals, they are only required to warn the prescribing physician. The prescriber acts as the "learned intermediary" between the manufacturer and the patient. The reasoning behind this exception is common sense. The physician is informed of the risks and benefits of the prescription drug product by the manufacturer. The prescriber, who has full knowledge of the patient's medical condition, then chooses the best products for the patient's needs.

There are two problems with the analysis of this line of Learned Intermediary cases. Generally, these cases hold that the doctrine covers both the judgment of the physician in weighing what drug therapy to use and that the physician is responsible for deciding what facts or warnings to give to the patient. By applying this doctrine to pharmacists, courts have said that pharmacists have no duty to warn patients about possible side effects of the medications they dispense. While it makes sense to reserve the decision on what therapy to use for the physician, it does not make sense to extend the doctrine so that only the physician must warn the patient about possible hazards of the drug. Especially since the passage of OBRA '90. The second problem is that most of the Learned Intermediary cases were decided prior to the passage of OBRA '90. One could argue that those cases are not relevant to today's pharmacy practice because the rules have changed.

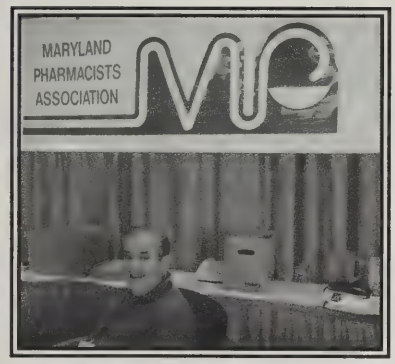
What did the court decide? The court answered both questions in the negative. The court correctly decided that the Learned Intermediary Doctrine places the responsibility for therapy choices squarely on the physician. However, on the question of the duty to warn, the court held that the Learned Intermediary Doctrine means that pharmacists, when filling a facially valid prescription, have no duty to warn their patients about risks or possible side effects of the drug *except* when ordered on the prescription or when expressly required by another statute or regulation. Is OBRA '90 such a statute? Arguably so, but the court doesn't address this question directly. The opinion states that the question was answered in the negative implying that there is no duty on the part of the pharmacist to warn a patient in Alabama. However, the explanation of the ruling provides for exceptions to this ruling.

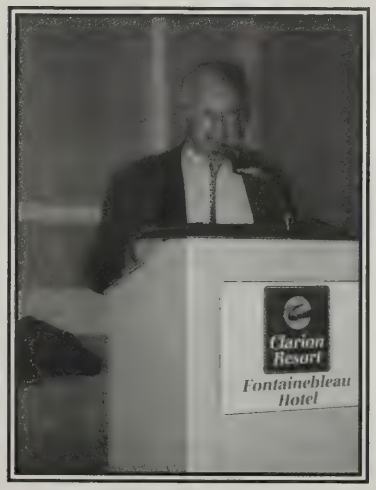
In summary, this case looks on the surface to provide some protection for pharmacists through the application of the Learned Intermediary Doctrine. In this case, it is apparent that the pharmacist should not be required to counsel a patient to whom the prescription is not dispensed when that patient is later instructed to use the prescription by the physician directly. However, the case leaves too many questions without clear answers to help the practicing pharmacist know when he/she is required to warn their patients about the possible side effects of a prescription being dispensed. While the end result in this particular case is probably correct, pharmacists, generally, fail again to receive a clear explanation of their responsibility to their patients and patients' families.

© Don R. McGuire Jr., R.Ph., J.D. is Assistant General Counsel, at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

MPhA 122nd Annual Convention in Pictures





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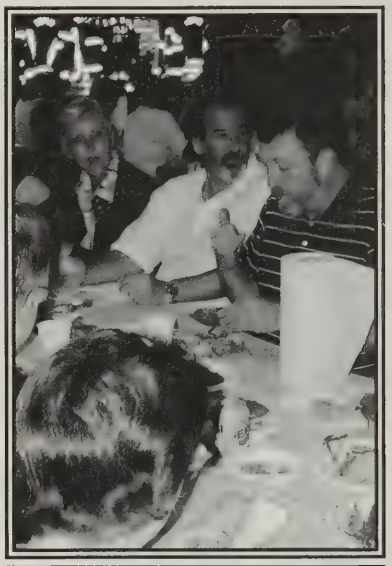

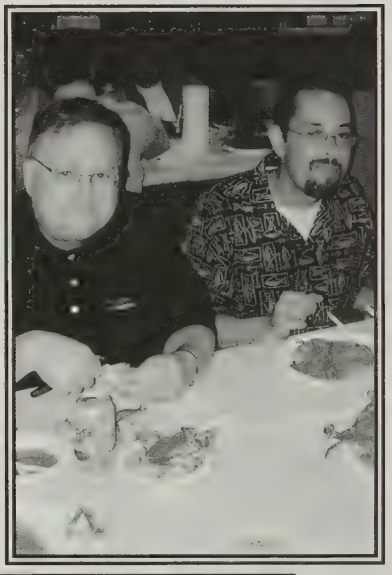

Capecitabine and Warfarin: A Dangerous Combination

John Bullinger, PharmD.

During a clinical rotation at a major Baltimore hospital, I was presented with a case involving a seventy year-old gentleman who, because of a history of atrial fibrillation, had been taking warfarin for the past year. His recent INR, which had been very steady over the last six months at 2.5, had increased to 3. Upon further questioning, he stated that he had started another course of therapy of capecitabine for colon cancer. This gentleman had used capecitabine previously while on warfarin, and two weeks after therapy stopped, his INR skyrocketed to 9.9 over a one-week period, increasing the likelihood of hemorrhage. While this combination of medications is sometimes necessary, it is important to know what can be done to minimize this effect as well as how to treat it if it occurs.

Capecitabine is an oral fluoropyrimidine carbamate that is converted to fluorouracil (5-FU) preferentially in colorectal tumors [1]. While the mechanism of action of 5-FU is unclear, it is thought to interfere with the metabolism of warfarin through the synthesis of the hepatic cytochrome P-450 2C9 [2]. This results in an increased effect from warfarin leading to an increased International Normalization Ratio (INR). Post marketing exposure to Xeloda has revealed that there is a potentially dangerous interaction with warfarin and in November 2001 the FDA added a Black Box warning to the packaging insert of Xeloda. The warning includes this phrase: "Post marketing results have shown clinically significant increases in prothrombin time (PT) and INR in patients who were stabilized on anticoagulants at the time Xeloda was introduced." [3]

While the exact extent of this reaction is not known, there are several cases that have been reported that may help to predict the extent to which the INR may increase. Kolesar et al. reported on five patients in the same facility that experienced an increased INR while taking warfarin for chronic atrial fibrillation and 5-FU. Two of these patients had to be hospitalized for retroperitoneal bleeds and all patients had an increased INR, which was seen 16 to 41 days after starting therapy. The average dose reduction for these five patients was 44% [4]. Chlebowski et al. reported that during a clinical trial of twenty-five patients taking 5-FU and warfarin to maintain a therapeutic INR, three patients had bleeding episodes requiring transfusion [5]. While these two reports included patients taking warfarin for the maintenance of a therapeutic INR, there is one case reported where a patient taking mini-dose warfarin for prophylaxis against catheter-associated thrombosis and 5-FU had an increased INR [2]. These cases would suggest that all patients taking capecitabine and warfarin should be closely monitored, preferably at least weekly and any increase in INR or PT should be aggressively handled.

If a patient presents with an INR substantially above therapeutic levels, treatment should be initiated to bring the INR to within normal limits. There are several treatment options available: Fresh frozen plasma (FFP) or vitamin K (phytonadione) IV, IM or oral. The National Institutes of Health recommends vitamin K for use in patients who are over anti-coagulated from warfarin unless they are actively bleeding or require emergency treatment. These patients should receive FFP to achieve immediate hemostasis [6]. Selecting the appropriate method of delivery for vitamin K is based on the severity of the situation. Watson et al reported that intravenous vitamin K was faster than oral delivery [7]. They measured INR at 4 hour and 24 hour intervals in 64 patients. At 4 hours, 5 of 49 patients had an INR of less than 4 in the oral group and 8/12 for the IV group. At 24 hours, 33 of 49 and 12 out of 12 for the oral and IV groups respectively [7]. This clearly demonstrates that the IV method has a faster onset. Crowther et al. conducted a randomized controlled trial comparing oral and subcutaneous vitamin K [8]. They looked at 51 patients with an INR between 4.5 and 7.6 (mean 5.8). At 24 hours, 15/26 (58%) of patients who received the oral dose and 6/25 (24%) of patients who received the subcutaneous dose had an INR between 1.8 and 3.2 [7]. This clearly shows that oral dosing has a greater effect at lowering the INR within 24 hours.

Since each patient is different, care should be taken with each case. Patients need to be monitored and evaluated individually to determine their risks when taking capecitabine and warfarin concurrently. In the case of the patient I encountered, his warfarin dose was immediately reduced 50% (14mg/week to 7mg/week). After one week, he was seen again with an INR of 2.5. His warfarin was reduced again to 4 mg/week and on follow up one week later, his INR was 2.1. Aggressive, proactive reduction in his warfarin dose kept his INR within therapeutic range and he was able to continue both medications without any serious complications throughout his therapy.

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Surviving a Third-Party Audit
A Guide for Every Pharmacist

David G. Miller, P.D.

The day can't possibly get any worse. Your partner is leaving tomorrow on a three week vacation. The delivery driver just called to say he had been in an accident. The order from the wholesaler, the one with the vaccines you *promised* to the doctors next door by noon, hasn't arrived and it's already 12:30. Meanwhile, your computer is telling you that Mrs. Allan's prescription is no longer reimbursable even though you filled it for her only two weeks ago.

While juggling the phone with one hand, you open an envelop from Mega-HMO. Finally, you think, here's the check they've been promising for weeks. Think again. It's a letter informing you that Mega'HMO's auditors will be coming to your pharmacy next Wednesday to review your prescription files for compliance with their contract.

In a daze, you pick up on the other phone line. "Hello, this is Carol from BDS Prescription Plan," says a no-nonsense voice. "Representative from our Review Department will be in your area two weeks from now. They will be arriving at your pharmacy for a complete audit of BDS prescriptions on Monday morning at 9:00 am.

Sound familiar?

First Things First

The first thing to do after receiving notice about a third-party audit is to calm down! Most pharmacists feel a moment of panic whenever an audit is requested. You begin imagining problems… have you forgotten something? what are they looking for? what have I done wrong?

Actually, you probably haven't done anything wrong. Just as you are obligated to allow audits of your pharmacy's records by third-parties, those same third-parties may be required by their contracts with clients to audit certain number of pharmacies each year. There may be a number of reasons for why your pharmacy was selected. Your pharmacy may do a high volume of prescriptions with a specific third-party—especially if you are located near a large employer, a clinic or a medical center. You may have several patients using that third-party who have multiply, high cost prescriptions. Or, more commonly, your practice was just picked at random. So, what do you do now?

If you are notified by telephone that you are about to be audited, get the name, telephone and FAX number of the person before proceeding with any more conversation. Inform them that you will need to check your schedule to determine if the time they have selected is appropriate for your pharmacy and your schedule. An audit is a serious process and one that shouldn't be handled or scheduled as if it were a call-in refill. Don't be pressured into confirming a date and time until you are satisfied that it meets with your schedule. If necessary, tell the caller that you will contract them shortly to confirm the date and time, check your schedule, and then call them back.

If you are notified in writing, again make sure that you have the name, telephone, and FAX number of the person in charge of coordinating the audit. This usually appears within the notice or on the company's letterhead.

Read the Contract

Next, get out the most recent copy of your contract with the third-party. If you don't have one, get one. Call the third-party and ask that a copy be sent to you immediately. Now would be a good time to check to see that you have copies of <u>all</u> your third-party contracts on file in the pharmacy. Pharmacists, unfortunately, tend to be some what cavalier about keeping third-party contracts. Remember that they are legal documents to which you have obligated your pharmacy, and possibly yourself, and should be treated the same way you would treat your lease agreement or mortgage papers.

Read the contract. All the way though. Does the contract permit audits? (They almost always do) Does the contract say anything about that the things auditors will be looking for? Are you completely familiar with the requirements of the contract? You may also need to review the third-party's policy and procedures manual, if any was provided, as often this manual is referred to and made part of the actual contract.

Scheduling the Audit

Most third-party contracts with audit clauses include phrases such as "regular business hours" and "reasonable." This means that while the third-party has a right to audit, you have the right to have the

audit conducted in such a manner as to not significantly intrude on your transaction of business and patient care. For example, if Monday morning is hectic time for an audit and Tuesday afternoon is better, you have the right to request that the audit schedule be changed. Also, and this is especially important for small practices, if you will need to schedule additional personnel to be on hand during the audit, you have the right to ask for a schedule change.

When you call the third-party to confirm the audit, make sure you obtain the following information:

- Day and date of the audit.
- Start and end time of the audit.
- The name(s), company if different from the third-party, address, telephone and FAX phone numbers of the auditor(s).
- Written confirmation from the third-party to be sent to your pharmacy via FAX or mail immediately.

Asking About Records

Your next step is to contact he actual auditor(s) if they are different from the person who scheduled the audit. Confirm the date and time of the audit with them, especially if you have changed the originally proposed schedule and if you have been working with another contact person within the third-party.

So far so good; but, this next part is more difficult. Ask the auditors to provide you with a list of prescription numbers that they will want to research? Why?

First, though the third-party has the right to review all documentations including the patient's profile, the original prescriptions, and the signature log from any claim that you submitted to the third-party, they do not have the right to see any prescriptions or profile information from any other patient. For example, PCS may not review or peruse the prescriptions records for Blue Cross patients nor may they review the records for your cash paying customers.

You, as the pharmacist, have the responsibility of keeping your patient's prescription records confidential. Imagine the ramifications of an auditor flipping through your prescription files and discovering that their neighbor —a cash paying customer—is receiving AZT, chlorpromazine and diazepam. What might you liability be if that auditor went home and proceeded to tell the neighborhood about your patient?

Second, having the prescription numbers in advance enables you to pull those records to have them available for the auditors when they arrive. It's more efficient and helps save you time and effort in tracking down files and records if this can be done ahead of time.

Be aware, however, that in most cases the auditors will not want to give you the prescription numbers for fear that you could then pull these records and correct errors or improprieties. A compromise to propose is that the auditor provide the pharmacy with the majority of prescription numbers in advance and that the remaining numbers will be pulled at the time of the audit. This system speeds up the process for the pharmacist while still satisfying the auditors' concerns about "tampering." Whether or not you are successful in obtaining prescription records in advance, you should insist on receiving that information.

In addition to a list of prescription records, ask what other specific information or data the auditor will require. The checklist on this page lists some of the most commonly requested items. Whether or not you are facing an audit, the time spent today in putting copies of these documents into a readily retrievable file folder is a wise investment for tomorrow.

Before you conclude your conversation with the auditor, ask how long they anticipate spending in your pharmacy. As you may wish to have additional stag on hand during the audit, this time frame will give you some idea of scheduling needs.

Audit Checklist

Do you have access to or know where you can find…

- ☐ Most recent copy of the third-party pharmacy contract and any plan data sheets or procedures manual sent to you from the third party?
- ☐ Third-party prescription logs, including logs for delivered prescriptions if you have delivery or mail order services?
- ☐ Pharmacy licenses and permits?
- ☐ Liability insurance policies for both the pharmacy and professional liability insurance policies for pharmacists?
- ☐ Copies of rejected or unpaid claims from the auditing third-party as well as any documentation you may have regarding problems with the third-party's payments, processing system, etc.?

The Actual Audit

The bid day finally arrives and do the auditors. Before beginning the audit, ask for identification from the auditor(s) and one of their business cards for your files. Keep these along with your contract and any written communications you have received from the third-party about this or previous audits.

The first rule of conducting an audit—one that is broken by just about every pharmacist—is to never allow the auditor access to your records without close supervision from pharmacy personnel. Pharmacists have called MPhA after receiving a third-party audit report that requests back-payment for claims. During the course of their audits, the pharmacists allowed the auditors to look at any and all prescriptions, the auditors were able to determine that the pharmacy was not giving them the lowest price. Even though it means having additional staff on hand, and possibly tying you up for an entire day, you or another pharmacist should sit down with the auditor, extract the information they request and only that information, and personally give it to the auditor. Remember, you have an obligation to preserve your patients' prescription history confidentiality. Likewise, you also have an obligation to protect your business that could be jeopardized by an auditor on a "witch-hung," willing to use any information in any way to recoup money for their business.

If during the course of the audit you and the auditor discover that a mistake has been made on a prescription or a claim, be sure that you record what the mistake or problem is and what explanation, if any, you give to the auditor. Bear in mind that because most third-party auditors are not familiar with Maryland's pharmacy laws and regulations, they may raise questions about how you record information.

For example, one pharmacist told the MPhA office about an auditor who wanted to deny payments for all refills previously submitted to the third-party because the pharmacist had only recorded them in the computer and not on the back of the actual prescription. The auditor didn't believe that this was a legitimate method for documenting refills until the pharmacist was able to show that the Maryland State Board of Pharmacy considered this system acceptable. Therefore, you, as the pharmacist, should have on-hand during the audit a copy of the most current pharmacy laws and regulations.

Before the audit is concluded, make sure that you show the auditor any rejections or denied claims from the third-party. Also make sure you show the auditor any records of outstanding claims that you have not been paid for. Ask for explanations as to why the claims were rejected, denied, or why you have not received payment. Give copies of these to the auditor and ask that they be made part of his or her final report. Ask also that you received a written copy of the auditor's final report. Ask when you should expect the report and what appeals process if available should it become necessary.

After the Audit

Once the audit is finished, put the copies of your notes plus any material given to you by the auditor with your contract. If you do not receive the written report from the auditor you requested by the time promised, call and ask about the status of your audit. Don't be surprised if you don't hear anything—that's generally a good sign that means everything was pretty much acceptable.

However, there are times when the audit doesn't go smoothly and the third-party expects to be reimbursed for prescriptions that they believed were inappropriately paid by them to your pharmacy.

Some third-parties use an extrapolation method to determine whether they are due money from you. Their calculations, for example, would say that since you had errors or discrepancies on ten percent of the claims audited, ten percent of the total claims submitted and paid for by the third-party must also be in error. Under no circumstances should you accept this type of audit "blackmail."

If you receive a report/bill for an amount based on audit extrapolated figures, you should refer to the notes you took during the audit. Did you have reasonable explanations for any discrepancies on prescriptions or records? What was the auditor's response to your explanations at the time of the audit? Ask for, and if necessary, demand a complete listing form the third-party of prescriptions with discrepancies and exactly what they are.

Generally, a third-party is willing to negotiate some on what they believe you owe them. At this point, and especially if their claim against you is significant, you should contact your pharmacy's attorney for assistance. Don't make the mistake of some pharmacists and just send the third-party a check without first obtaining legal advice and exhausting the third-party's appeal process.

Conclusion

Surviving a third-party audit can be relatively painless if you are properly prepared. Remember the basic rules: assert your right to have the audit conducted at a reasonable time that doesn't impose on your business nor on your patients, be honest with the auditor, never

volunteer information, be familiar with Maryland's pharmacy laws and regulations, and never allow the auditor to have free access to your prescription files or records. ***And, if in doubt or if you need assistance, take advantage of the Maryland Pharmacists Association's resources and give us a call.***

Audit Rules To Remember

- Never allow the auditor access to records or files that do not pertain to the third-party or its customers.
- Always request identification from the auditor before allowing them access to your records.
- Never volunteer information for which the auditor has not asked.
- Always take notes during the audit about problems or questions raised by the auditor and your explanations, if any.
- Never lie or attempt to bluff you way through an audit. If you don't have any answer to an auditor's question, tell him or her when you will have an answer and them follow through.
- Always have a copy of the Maryland Pharmacy Laws and regulations on hand to reference in case of questions.

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Continuing Education for Pharmacists

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Patient Counseling: SARS, Here Just Today . . . or Here to Stay?

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this lesson is to provide background information on Severe Acute Respiratory Syndrome (SARS) to assist pharmacists in answering patients' questions.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. discuss the impact of SARS on U.S. and world health;
2. exhibit knowledge of the epidemiology, pathogenesis and clinical presentation of SARS;
3. identify infection control measures and recommendations for preventing SARS; and,
4. select from a list appropriate advice to convey to patients and/or others who inquire about SARS.

This lesson is provided by an educational grant from

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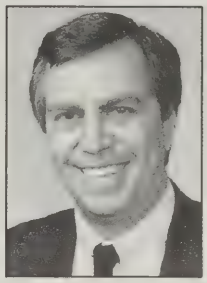

Wuest

The world learned about a new epidemic in March 2003 when the World Health Organization (WHO) issued a global health alert. An unknown illness mimicking influenza, called Severe Acute Respiratory Syndrome (SARS), had infected more than 6500 individuals and killed an estimated 461 persons worldwide by March 5. The disease could be traced back to November 2002. At that time, a businessman in Guangdong Province, southern China, became intensely ill. He was hospitalized and treated for suspected atypical pneumonia. Despite antibiotic therapy, the patient's condition worsened and he died. Soon, four health care workers who cared for him became ill with the same symptoms. Over the next three months, additional locales of infections were identified, and Chinese hospitals were soon deluged with patients suffering from this puzzling new affliction. Of concern to the WHO and health care leaders everywhere was that information on the epidemic was withheld by the Chinese government until the disease was transported into Hong Kong by a physician who developed the classic symptoms, was hospitalized with SARS, and died despite treatment.

As of August 2003, SARS has infected an estimated 8439 persons worldwide, with 812 deaths. Of these, the U.S. has recorded 192 (159 suspected, 33 probable) infections with no deaths; Canada (Toronto, primarily) has recorded 250 infections and 38 deaths. Hot spots for the epidemic are China, Hong Kong, Taiwan, Singapore, and Vietnam.

Epidemiology

There is strong evidence that a novel coronavirus is the etiologic agent of SARS. It is possible that other pathogens may be involved in certain cases of SARS. The virus' genome has been sequenced by scientists at the Centers for Disease Control and Prevention (CDC) and others, and the virus is provisionally termed SARS-CoV. Its approximate 30,000 nucleotides make the SARS-CoV the largest of any known RNA virus.

Coronaviruses are ubiquitous and a cause of respiratory and enteric disease in many animal species, including cats, dogs, chickens, pigs, and cattle. These viruses have been associated with upper respiratory tract infections, and sometimes pneumonia, in humans. Although they are the causative pathogens for up to 30 percent of common colds in humans, coronaviruses rarely cause lower respiratory tract infections.

The SARS coronavirus may have emerged as a mutant of a human viral strain that acquired new virulence factors. It may have arisen as a mutant of an animal coronavirus that crossed over to human hosts. It may have been formed as a recombinant strain of two human coronaviruses or a combination of human coronavirus and an animal coronavirus.

Antibodies to the coronavirus were detected in serum obtained from patients with SARS during convalescence. They have not been found in serum samples collected and banked before the SARS epidemic. This suggests that the SARS coronavirus is new to humans. The nucleotide sequence of the SARS-CoV genome differs greatly from sequences of other known coronaviruses; thus, it is probably neither a mutant of any known coronavirus nor a recombinant of known coronaviruses. Expert opinion at present is that it is a previously unknown coronavirus. It probably originated in a nonhuman host, and somehow acquired the ability to infect humans.

Pathogenesis and Clinical Presentation

SARS is spread primarily by close person-to-person contact. Most cases have involved persons who lived with or cared for a SARS-infected individual, or had direct contact with infectious material or respiratory secretions from a person infected with SARS. SARS may potentially be spread by touching the skin of contaminated persons or objects. This occurs when an infected person coughs or sneezes respiratory droplets onto themselves, other people, or nearby surfaces. Environmental surfaces (e.g, floors, countertops) are generally not involved in transmission of microorganisms. Some surfaces that are touched frequently (e.g., doorknobs, telephone receivers, lavatory surfaces, TV-remote controls) may serve as important reservoirs of viral contamination, if even for a few hours. When these surfaces are touched, the infectious virus can be conveyed from the fingers or hands to the eyes or mucous membranes of the nose or mouth, or onto other surfaces or objects to be contacted later. SARS may also spread through the air or by other means that have not yet been identified.

Large-droplet transmission is important in the transmission of SARS and suggests that intimate contact with an infected patient is required. The unusually rapid spread, however, suggests that airborne transmission can also occur through small droplets (<10μm in diameter). Such small-size droplets, which are key to the transmission of influenza, measles, and tuberculosis, permit the organisms to travel directly into the alveoli of the lungs of contact persons.

Most cases of SARS in the U.S. have been traced to travelers returning from places where SARS outbreaks have been reported. The majority of patients infected with SARS have been adults, aged 25 to 70 years of age, who were otherwise previously healthy. Only a few suspected cases of SARS have been reported in young people <15 years of age. To date, there have been only a limited number of cases in this country that occurred as a result of spread to close contacts such as family members and health care workers. There is at present no evidence that SARS is spreading widely within any community in the U.S.

The incubation period is typically two to seven days; however, isolated reports have suggested an incubation period as long as 10 days. A prodrome (early warning symptoms) of fever (>100.4° F) is noted. Fever is sometimes associated with chills and rigors, and may be accompanied by other symptoms including headache, malaise, and myalgia. Early in the illness, some individuals encounter mild respiratory symptoms. Rash and neurologic findings are typically absent. Sôme patients have reported diarrhea during the febrile prodrome. Renal function remains normal in most patients.

A lower respiratory tract phase of symptoms begins after three to seven days with onset of a dry, nonproductive cough or dyspnea (difficult or labored breathing). This may be accompanied by or progress to hypoxemia (reduced oxygen content in the blood). The respiratory illness is sufficiently severe to require intubation and mechanical ventilation in up to 20 percent of cases. The fatality rate in persons whose illness meets the current WHO definition of SARS is approximately 5 percent; however, the WHO estimates this could reach 10 percent. Some fear is warranted, but the present mortality rate is, in fact, close to that seen with community-acquired pneumonia in this country. Moreover, the death rate at present remains a small fraction of the estimated 35,000 deaths from influenza alone in the U.S. each year. A major difference between SARS and influenza is that the former is a killer of healthy adults. Influenza is lethal primarily to the elderly and those with immune deficiency disorders.

Chest radiographs may appear normal throughout the febrile prodrome and the course of illness. The patient's lymphocyte count often decreases early in the course of the disease (lymphopenia). White blood cell counts have generally been normal or decreased (leukopenia). At the peak of the respiratory phase of the illness, approximately one-half of patients exhibit leukopenia and thrombocytopenia (low platelet counts). Elevations in creatinine phosphokinase and hepatic transaminases have been noted early in the respiratory phase.

The severity of symptoms is highly variable. Some close contacts of patients with SARS have developed a similar illness, although the majority have remained well. Later, they developed mild, febrile illness without respiratory signs or symptoms. This suggests that the infection may not always progress to the respiratory phase.

SARS Case Definition

The definition of SARS includes consideration of clinical, epidemiologic and laboratory criteria. These are outlined in Table 1. The WHO defines a *suspected* case of SARS as an individual, with documented fever (temperature >100.4° F) and lower respiratory tract symptoms, who had contact with a person

Table 1
Case Definition for Severe SARS

Clinical Criteria
- Asymptomatic or mild respiratory illness
- Moderate respiratory illness
  - -temperature of >100.4° F, and
  - -one or more clinical findings of respiratory illness (e.g., cough, shortness of breath, difficulty breathing, or hypoxia)
- Severe respiratory illness
  - -temperature of >100.4° F, and
  - -one or more clinical findings of respiratory illness (e.g., cough, shortness of breath, difficulty breathing, or hypoxia), and
    - -radiographic evidence of pneumonia, or
    - -respiratory distress syndrome, or
    - -autopsy findings consistent with pneumonia or respiratory distress syndrome without an identifiable cause

Epidemiologic Criteria
- Travel (including transit in an airport) within 10 days of onset of symptoms to an area with current or previously documented or suspected community transmission of SARS, or
- Close contact within 10 days of onset of symptoms with a person known or suspected to have SARS

Laboratory Criteria
- Confirmed
  - -detection of antibody to SARS-CoV in specimens obtained during acute illness or >21 days after illness onset, or
  - -detection of SARS-CoV RNA by two separate assays, by using separate specimens for assay, or
  - -isolation of SARS-CoV
- Negative
  - -absence of antibody to SARS-CoV in convalescent serum obtained >21 days after symptom onset
- Undetermined
  - -laboratory testing either not performed or incomplete

Source: www.cdc.gov/ncidod/sars

believed to have had SARS or a history of travel to an area of documented outbreak. A *probable* case is a suspected case, along with positive chest radiographic findings for pneumonia, acute respiratory distress syndrome (ARDS), or any unexplained respiratory illness that terminates in death, with autopsy confirming ARDS without identifiable cause.

Treatment

There are no specific treatment recommendations at this time. A specific diagnostic test is not yet available. Therapy is based on practical experience, and includes drugs of choice that are used for other cases of community-acquired pneumonia of uncertain etiology. Choice of treatment is influenced by the severity of symptoms. Supplemental oxygen is recommended for hypoxia.

Therapy has included oral ribavirin, 1.2 g every eight hours. Ribavirin for intravenous injection is available through CDC, dosed at 8 mg/kg every eight hours. Ribavirin has broad-spectrum activity against some RNA viruses. Steroids have been administered orally or intravenously to patients in combination with ribavirin and other antimicrobials. Clinical benefit has yet to be established unequivocally by placebo-controlled trials, but anecdotal reports of efficacy continue to be reported.

Health researchers are searching for an effective SARS vaccine. Experts advise that a vaccine suitable for humans is years away. Even if a vaccine is developed, there is no assurance the new vaccine would effectively control SARS. At the same time, there is reason to be optimistic because vaccines are successful in preventing coronavirus infection in animals.

Clinicians who evaluate suspected cases should follow standard protocol for protecting against contact and airborne particles. When persons suspected of SARS infection are identified, they should be reported to their state health departments.

Counseling Patients on SARS

Infection Control Guidelines. CDC has issued interim guidelines for controlling infection of SARS in health care and community settings. These precautions are recommended to minimize the potential for transmission until the epidemiology of disease transmission is better understood. All persons in contact with suspected SARS patients should practice good hand hygiene, including hand washing with soap and water, or if the hands are not visibly soiled, using alcohol-based handrubs as an alternative to washing.

Inpatient Setting. If a suspected SARS patient is admitted to the hospital, infection control personnel should be notified immediately and the following measures implemented.
- *Standard precautions* include good hand hygiene. Health care personnel should wear eye protection during patient contact.
- *Control precautions* include the above, plus wearing gown and gloves during contact with the patient or his/her environment.
- *Airborne precautions* involve maintaining the patient in an isolation room with negative pressure relative to the surrounding area. Persons entering the room should use an N-95 filtering disposable respirator. If airborne precautions cannot be implemented fully, patients should be housed in a private room. All persons entering the room should wear a N-95 respirator. If unavailable, a surgical mask should be worn. Surgical masks will protect against inhalation of large droplets. Surgical masks may not protect against fine aerosol particles mainly because they permit leakage around the mask. A mask that is applied correctly should fit tightly around the mouth and nose and resist fluid penetration. Standard and control precautions should be implemented for suspected SARS patients, regardless of the availability of facilities for airborne precautions.

Outpatient Setting. Infection control measures for outpatients should include:

Table 2
Information for Persons Suspected of having SARS or Symptoms of SARS

- If you become ill with fever or respiratory symptoms (e.g., cough or shortness of breath), a visit to a health care provider is strongly recommended. Tell the provider about your symptoms prior to going to the office or emergency room so arrangements can be made, if necessary, to prevent transmission to others there. Do not travel while sick and limit your contact with others as much as possible to help prevent the spread of infectious illness.
- If you become ill, cover your mouth and nose with a tissue when coughing or sneezing. If possible, wear a surgical mask during close contact with healthy people to prevent spread of infectious droplets. If you are unable to wear a surgical mask, other persons should wear surgical masks when in close contact with you.
- Avoid sharing eating utensils, towels, and bedding with others, although these items can be used by others after washing or laundering with soap and hot water.
- Environmental surfaces (e.g., toilets, sinks) soiled by body fluids should be cleaned with a household disinfectant according to the manufacturer's instructions; gloves should be worn. Wash your hands afterwards and discard the gloves.
- Other close contacts staying with a person with SARS do not need to restrict their outside activities unless they develop symptoms of SARS.
- All close contacts staying with a person with SARS should carefully follow recommendations for hand hygiene (e.g, frequent hand washing or use of alcohol-based handrubs), particularly after contact with respiratory secretions, urine, or feces.
- Disposable gloves are not intended to replace proper hand hygiene. Immediately after contact with body fluids, gloves should be removed and discarded, and hands should be cleaned. Gloves must never be washed or reused.

- Persons requesting medical assistance for an acute respiratory infection should be questioned about possible exposure to another person(s) with SARS, and/or about recent travel to an area with SARS. If SARS infection is probable, the patient should wear a surgical mask over his/her nose and mouth. If this is not possible, the patient should be instructed to cover his/her mouth with a disposable tissue when talking, coughing, or sneezing. The patient should be isolated as soon as possible (see Airborne precautions, above).
- All health care personnel should wear a N-95 respirator while tending to patients with probable SARS. In addition, they should follow all standard precautions as described above.

Residential Setting. Patients should wear a surgical mask during periods of contact with others. If this is not possible, other household members should wear surgical masks when in close proximity with the patient. Household members tending to the patient should adhere to good hand hygiene. These basic precautions should be followed for 10 days after respiratory symptoms and fever are gone. During that period, SARS patients should remain at home.

Travelers to SARS Areas. Two types of notices to travelers have been issued. A *travel alert* does not recommend against travel, but informs them of a health concern; a *travel advisory* recommends that all nonessential travel be deferred. Travelers in an area with SARS should observe strict hand washing and hygiene to protect against infection. In addition, travelers should avoid close contact with large crowds as much as possible to reduce the chance of infection. The routine use of masks or other personal protective equipment is not specifically recommended while in public areas, but may be a reasonable precaution.

Individuals Who Suspect Infection with SARS. Persons with symptoms of SARS (fever >100.4° F, along with a cough and/or difficulty breathing) should consult a physician. They should tell the physician about any recent travel to areas where SARS has been reported and whether there was contact with someone who had these symptoms. Table 2 includes advice for persons with suspected symptoms.

The Future

Health experts caution against complacency over the relatively low number of cases of SARS in the U.S. since the infection will likely reappear during winter months with more potentially serious consequences. Because the virus continues to persist in nations with poor sanitation and unsophisticated public health infrastructure, there is a strong probability that SARS will remain a global threat for many years to come. It remains to be seen whether the number of cases will grow exponentially or eventually level off and decline. SARS has been compared to HIV, which taught the world a valuable lesson.

The following SARS websites include up-to-date information: www.cdc.gov/ncidod/sars or www.who.int.

toxtidbits
1-800-222-1222
the maryland poison center's monthly update. news. advances. information.
June 2004

Lionfish Envenomation

The lionfish (*Pterois volitans)* is a tropical fish belonging to the Scorpionfish family and native to the Pacific and Indian Oceans. They have recently been observed and captured off the East Coast of the United States, most likely from the release of captive fish. These uniquely beautiful fish are often purchased in pet stores or on websites and placed in home aquariums. Poisonings primarily occur when owners are stung on the hand when handling the fish or cleaning the aquarium; however, divers and fisherman in the Atlantic have also been stung.

Lionfish have distinctive red, maroon and white zebra-like stripes, fan-like pectoral fins and long dorsal spines. Adults can grow to 18 inches in length. There are glands in the base of the spines which release a venom when disturbed. The venom, a complex mixture of proteins, travels along the spine and is injected through a puncture wound created by a spine.

Immediately after being stung, excruciating, throbbing pain occurs at the sting site and radiates to the affected extremity. The pain peaks in intensity in 60-90 minutes and can persist along with variations in sensation for hours, days, and sometimes weeks. Edema, erythema, ecchymosis, pallor, and induration may be visible. Systemic effects are rare and include headache, nausea, vomiting, abdominal pain, diaphoresis, dyspnea, hypotension and syncope.

Treatment consists of immersion of the affected area in hot (110°-113° F) but not scalding water for 30-90 minutes or until the pain subsides. The venom appears to be heat labile and inactivated by heat. Oral analgesics, local wound care and supportive care for systemic effects should follow if needed.

Call the Maryland Poison Center for assistance in identifying and managing fish stings: 1-800-222-1222.

Lisa Booze, PharmD, CSPI

DID YOU KNOW THAT... **There were over 2800 exposures to fish and other aquatic life reported to poison centers in 2003?**

These exposures included stings from scorpionfish (lionfish, zebrafish, stonefish, weeverfish), catfish, leatherjacks, stingrays, coelenterates (jellyfish, sea anemones, sea nettles, corals), sponges, and cone shells. Most resulted in minor-moderate effects such as pain, local wounds and mild systemic symptoms.

Maryland Poison Center
University of Maryland School of Pharmacy

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: SARS, Here Just Today...or Here to Stay". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 9/15/06. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-03-009-H01.

Name_____

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for

1. There is strong evidence that the etiologic agent of SARS is a:
   a. coronavirus.
   b. herpesvirus.
   c. pneumovirus.
   d. rhinovirus.

2. Expert opinion at present is that the virus referred to in question #1 is most likely to be a:
   a. mutation of a known virus.
   b. virus that escaped from a biologic weapons research facility.
   c. recombinant of a known virus.
   d. virus that until recently only infected animals.

3. Most cases of SARS in the United States:
   a. have occurred as a result of spread to close contacts such as family members.
   b. involve young people under 25 years of age who were otherwise previously healthy.
   c. have been traced to travelers in places where SARS outbreaks have been reported.
   d. involve patients already infected with human immunodeficiency virus.

4. Which of the following is LEAST likely to be a symptom of SARS infection?
   a. Malaise
   b. Rash
   c. Myalgia
   d. Headache

5. The symptom *dyspnea* refers to:
   a. labored breathing.
   b. upset stomach.
   c. dry cough.
   d. abdominal cramps.

6. Which of the following is NOT a clinical criterion for severe SARS?
   a. Radiographic evidence of pneumonia
   b. Hypoxia
   c. Respiratory distress syndrome
   d. Severe diarrhea

7. All of the following define a *probable* case of SARS EXCEPT:
   a. acute respiratory distress syndrome.
   b. history of travel to an area of documented outbreak.
   c. positive radiographic finding for pneumonia.
   d. unexplained respiratory illness resulting in death, with an autopsy confirming ARDS without identifiable cause.

8. Therapy for SARS has included which of the following drugs with activity against RNA viruses?
   a. Acyclovir
   b. Metronidazole
   c. Ribavirin
   d. Zidovudine

9. When a patient with SARS is cared for at home, basic hygienic precautions should be followed for which of the following number of days after respiratory symptoms and fever are gone?
   a. Three
   b. Seven
   c. Ten
   d. Fifteen

10. Which of the following types of notices to travelers recommends that all nonessential travel to an area with SARS outbreak be deferred?
   a. Travel advisory
   b. Travel alert

CORRECTION: The corrrect ACPE number for Patient Couseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.

CLASSIFIED

PEAC—Pharmacists' Education and Assistance Committee
401-706-7513

Lawbook—

In order to provide you with the legal information you need to practice pharmacy in Maryland, the Maryland Pharmacists Association (MPhA), Judge John Fader, and the Law Book Committee have collaborated to restructure and update the current publication entitled *Pharmacy Laws and Regulations for the State of Maryland*. The XI Edition is now available. The special features of this lawbook are:

- Updated and New Statutes and Regulations
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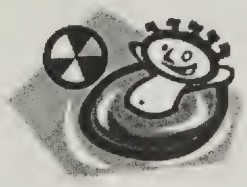
To order by credit card
call the MPhA office at 410-727-0746.

HIPAA Manual —

MPhA has teamed up with the National Association of Chain Drug Stores (NACDS) to provide a HIPAA Privacy Compliance Manual developed specifically for pharmacists and pharmacies. The 200 page manual includes summaries and outlines of the privacy requirements and samples of all the necessary forms, policies and procedures. Free updates for two years and a free subscription to the NACDS HIPAA newsletter (updates are included). The special rate for MPhA members is $295 (the non-member rate is $350.) This manual has been endorsed by the National Council of State Pharmacy Association Executives (NCSPAE). To order 800-833-7587 or 410-727-0746.

Want to Place an Ad?

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in the *Maryland Pharmacist* and reach more than 1,000 pharmacists for free. All ad copy is subject to approval and space availability. Reservations are due the first of the month preceding issue month. To place an ad, send your typewritten copy to MPhA, 650 W. Lombard Street, Baltimore, MD 21201-1572 or FAX to 410-727-2253.



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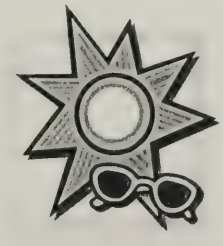

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Presidential Address

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Drug Therapy Management Series

"Part I: Focus on Medication Adherence"

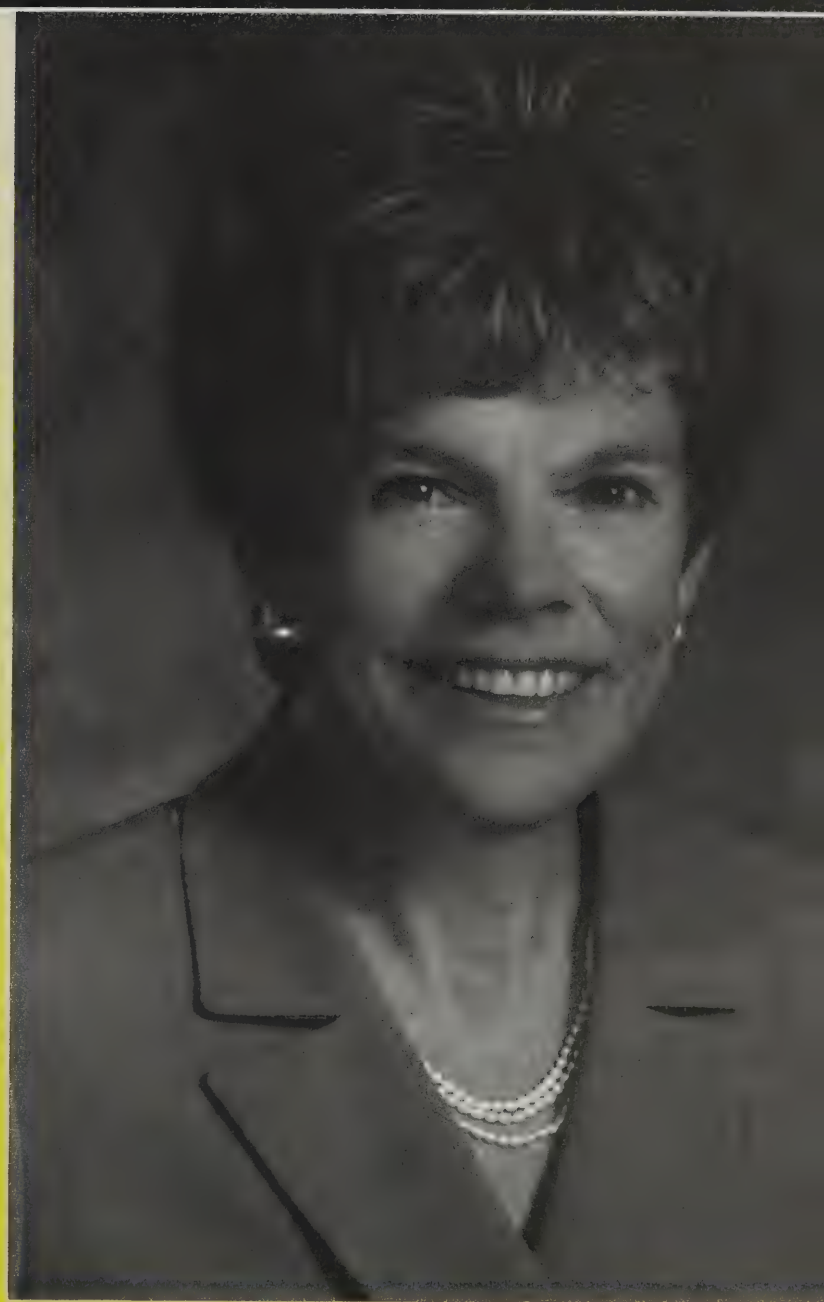
RX and the Law

"What do they think we are?"

Continuing Education

Patient Counseling:

"Smallpox: Part I: The Disease"



Cynthia Boyle, Pharm.D.
President 2004 - 2005

MARYLAND PHARMACISTS ASSOCIATION

JULY/AUG/SEPT 2004

Maryland Pharmacists Association

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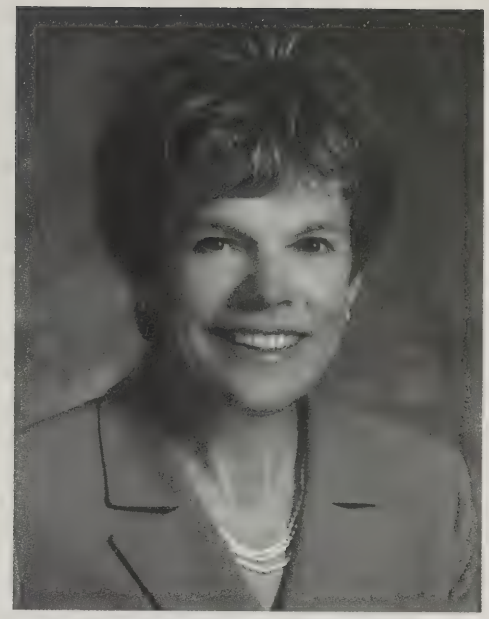
I am happy to share this address with those of you who were working or who were unable to attend the 122nd Annual Convention. I extend special thanks to Dr. Gary Hollenbeck who followed through on his promise made months before his new job responsibilities to serve as the Master of Ceremonies at the banquet. His humor, "fiery" musical theme selections, and clever audiovisual expertise made the banquet even more memorable. CB



Cynthia Boyle, Pharm.D.

"Light the Fire—Pass the Torch"

Presidential Address
Cynthia J. Boyle, Pharm.D.
June 14, 2004

Good evening family, friends, colleagues, and guests. As those of you who have previously served as MPhA president know, I am excited, a little scared, and profoundly thankful for the opportunity to lead this organization.

My address to you is not so much to list the agenda, which is the collaborative responsibility of the Board of Trustees, as it is to set the tone for the coming year. I was thinking of an island theme in Ocean City with title *Light the Fire—Pass the Torch*, but the metaphor also works in this year of the Athens Olympics.

As I looked through past issues of the *Maryland Pharmacist*, I was struck by the legacy our organization offers. We have a tapestry of talent. However, as I read presidential commentaries about issues and initiatives over the last decade, I also noted that many are unfinished and need our attention and vigilance. Through our legacy, we will honor our past; with our vision and actions, we will prepare for the future.

Legacy is important to me. B. Olive Cole, to whom our museum is dedicated, was known as the "First Lady of Pharmacy in Maryland." Dr. Cole graduated from the University of Maryland School of Pharmacy with a Doctor of Pharmacy in 1913 and was Professor Emerita of Pharmacy Administration. Her imposing stature and authoritative demeanor led to her notoriety as "one of the outstanding personalities in the world of pharmacy," according to Nathan Gruz. I felt a symbolic torch-passing when I learned that the museum dedication occurred the year I decided to pursue pharmacy, and that she died the year I graduated from the University of Oklahoma College of Pharmacy. As I prepared to attempt to impersonate her for our History of Pharmacy reception in the Kelly Building for Pharmacy Week last fall, I borrowed two of her personal possessions—faux smoky pearls and her visitor's pass for the U.S. Senate. They were tangible connections to her legacy in pharmacy education, organizational involvement, and advocacy.

The torch passing continues to new generations of pharmacists. One of my favorite photographs is the American Pharmaceutical (now Pharmacists) Association House of Delegates in 2001. Magaly Rodriguez de Bittner; Macary Weck, then a resident and now a faculty member at Albany College of Pharmacy; and I served as delegates. With flags, we displayed our Maryland affiliation and Ravens loyalty, while working to develop policies for the national organization. In another favorite photograph, even the blizzard of 2003 could not keep us from rescheduling Legislative Day for student pharmacists and pharmacists in Annapolis.

So what do I mean by "Light the Fire—Pass the Torch"? I mean quite simply "Get Involved, and Help Someone Else." There are already many torch-bearers among us, as you heard in the awards presentations. The job requirements for a torch-bearer are to:

- Maintain and improve professional competence,
- Develop connections within state and/or national professional organizations,
- Solve problems, and
- Serve as a role model to spread the word.

Nicki Brandt is a torch-bearer for her work in geriatrics. So is Jeff Sherr as a market innovator. Skip Amass has championed smoking cessation; Ron Sanford has a lifetime of service and commitment to MPhA; Mark Levi has a distinctive pharmacy career and spearheaded pharmacist immunization legislation during the last General Assembly. Your torches burn brightly to lead the rest of us.

Others who would like to apply for torch-bearer may need to get better prepared for the job.

Light the Fire with Professional Competence

As the complexity of healthcare has increased, professional competence is an expectation and a challenge. Pharmacists will need to move beyond episodic continuing education to Continuous Professional Development (CPD) as proposed by the Accreditation Council for Pharmacy Education (ACPE). Do you need certificate training to better care for your diabetic patients? Are you prepared to manage therapy, while providing medications? CPD requires analysis of professional needs and planning to meet those needs.

Light the Fire with Organizational Connection

This is another form of professional competence. Pharmacists who are not only members of pharmacy organizations, but who are also involved with them, get their money's worth. As we found out in our strategic planning surveys, our members value networking with colleagues, learning about solutions to problems and opportunities to improve practice, and avoiding the isolation that can be prevalent in pharmacy with long shifts and too few pharmacists to cover them.

Light the Fire through Problem-Solving

Apathetic individuals need not apply to be torch-bearers. We are challenged to overcome the many problems we see in our profession and in healthcare at large. Sometimes the next step begins with changing the inflection in a sentence. What can I *do*? becomes What can *I* do? We are empowered by helping one individual optimize his or her medication regimen, by helping our organization achieve sound financial support, and by seeking legislation to improve public health. By taking ownership of our profession, even when it involves focused legislative or corporate advocacy, we are compensated with professional satisfaction.

Light the Fire by Spreading the Word

Pharmacists are improving public health in our country, but we have to let others know what we do and how we can help. We can support Health People 2010 and the Leading Health Indicators. As you see, they range from eating well to preventing illness through immunizations.

- Physical Activity
- Overweight and Obesity
- Tobacco Use
- Substance Abuse
- Responsible Sexual Behavior
- Mental Health
- Injury and Violence
- Environmental Quality
- Immunization
- Access to Health Care

As an organization, let us pick one. Let's prepare pharmacists to immunize once the regulations are approved. Let's provide immunizations to prevent influenza for now. Let's work toward preventing other vaccine-preventable illnesses in the future.

Pass the Torch. This is essential not only for the future of the profession but to prevent torch-bearer burn-out. As we work in our particular

interest areas from publications or communications and practice initiatives to MPhA Foundation development and new practitioner networks, we need to invite people to join us. I estimate that 10% of our members are active, but with proactivity, 20% or more could be. Do we need to pass our whole torch, or just the flame? There are times when people need respite from leadership positions, and they can pass their torch for awhile. Their flame is not extinguished and through support and mentorship, they can fuel others' fires. The fire is brighter when many torches are lit than when one is passed from one to another, to another.

To identify and honor valuable mentors and torch-bearers among us, the MPhA Board of Trustees today voted to initiate the MPhA Mentor Award, to be awarded at subsequent awards banquets. The MPhA Mentor Award is created to recognize individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. Nominators will supply a brief narrative to describe the nominee as a role model, detail specific examples of mentorship, and illustrate the nominee's impact on the profession through his/her legacy of mentorship.

The photos which follow are from the 2004 Legislative Day. Several student pharmacists are posing with Govern Ehrlich. As Dean Knapp noted, "Our students did a marvelous job! They are informed, articulate, and assertive in expression their points of view to the many delegate and senators." They have received the fire and will pass the torch. In the other, we see representatives of the now five member organizations of the Maryland Pharmacy Coalition which was conceived in a 2000 resolution at the MPhA House of Delegates. MPhA, MSHP, MD-ASCP, and MPS invited the Student Government Association of the University of Maryland School of Pharmacy to become a fully participating, not a student, member of the coalition. The fire is brighter; there are more torch-bearers.

Thank you for indulging my extended igneous symbolism, and thank you for your many expressions of support. I look forward to implementing our strategic plan, and I will need your help to "Light the Fire, and Pass the Torch."

Welcome to the first of a four-part series on Drug Therapy Management. This series is intended to provide the community pharmacist with practical tips for improving care, generating revenue and increasing customer satisfaction.

"Drug Therapy Management Series: Part I: Focus on Medication Adherence"

Author: Catherine E. Cooke, PharmD, BCPS, with assistance from Susan Yi and Ji Hyun La Rose
Clinical Education Consultant, Pfizer
Clinical Assistant Professor, University of Maryland School of Pharmacy

Maryland is one of 40 states where pharmacists are authorized to practice drug therapy management.[1] This drug therapy management provision expands a pharmacist's scope of practice to allow for activities within the "parameters of a therapy management contract." A physician and pharmacist can enter into an agreement, i.e., a therapy management contract, that describes the activities a pharmacist can do for patients with a specific disease such as hypertension. In the case of Mr. Jones (see Case Example), the pharmacist could monitor Mr. Jones' blood pressure and if his blood pressure was not at goal, develop and implement a plan to improve it. Maybe Mr. Jones needs a dosage increase of one of his medications? Or, as we can see by the refill history, maybe Mr. Jones is not adherent and needs assistance with increasing adherence? There is suboptimal benefit from a medication not taken as intended. This first article focuses on Medication Adherence, often seen in the headlines as "America's Other Drug Problem.[2]

Case Example:
Mr. Jones is a regular customer at your pharmacy for over 10 years. He has had hypertension and been on antihypertensive therapy for as long as you have known him. He walks into the pharmacy and you realize you haven't seen him in a while. Mr. Jones explains that he suffered a stroke and was in the hospital last month. He hands you two prescriptions for his antihypertensive medicines. You realize that these are the same medications as before and, when looking more closely, you notice that over the past year, he has only had about six refills, each with 30-day supply. What do you do?

Adherence can be defined as the extent to which a patient's behavior, i.e. taking prescribed medication and implementing therapeutic lifestyle changes, coincides with the healthcare provider's recommendations.[3] More specifically, medication adherence is the use of the right drug in the correct dose at the right interval over the time frame intended by the prescriber.[4] Despite improved health care knowledge and increased access to health care information, non-adherence is still alarmingly high. About three out of every four Americans are non-adherent.[5] This figure is a result of the fact that 12% never fill their initial prescription, another 12% never take any of the purchased prescription, another 22% take less than what was prescribed and another 29% stop taking the medicine to completion.

The literature documents that patients who are more adherent have better health care outcomes. In the West of Scotland Coronary Prevention Study, subjects who were more adherent (i.e., defined as $\geq$ 75%) to statin therapy had a 32% reduced risk for death from any cause.[6] In addition to better outcomes, decreasing non-adherence prevents wasting of healthcare resources. One study examined community residents aged 65 years or older and demonstrated that antidepressants and antihypertensives are the second and third most costly wasted medications, respectively. If the costs of non-adherence in this study were extrapolated to national U.S. costs for those 65 and older, they would equate to over $1 billion dollars annually.[7]

What can be done? The strategies listed in Table 1 can be employed to assist pharmacists with improving medication adherence.[8]

Table 1 – Strategies to improve adherence

1. Education about the value/benefit of the medication
2. Teaching the patient about self-management (e.g., blood pressure or glucose monitoring
3. Refill reminders (e.g., telephone, electronic, mail etc.)
4. Adherence aids (e.g., pill boxes, calendars)
5. Simplification of dosing regimen (e.g., QD drugs, packaging)

Many Maryland pharmacists are already implementing these strategies. One strategy shared among community pharmacies is to call patients who are late getting refills. There are computerized databases—some of which are free, e.g., LATE (Longitudinal Adherence Treatment Evaluation[9]) that can assist with identifying these patients. Technicians can contact patients either by phone, e-mail or letter to let them know they are due for their refill.

Other strategies used by Maryland pharmacists are establishing personal relationships along with simplifying and tailoring medication regimens. As with Mr. Jones, the pharmacist has a personal relationship with him. When the pharmacist realized that Mr. Jones was non-adherent, he asked him, "Why?" Mr. Jones explained, "I didn't feel any different when I took them. Also, that one medicine I was supposed to take twice a day, and I never remembered to take it again at bedtime." The pharmacist called Mr. Jones' physician and suggested a once-daily medication in place of the twice-daily medication and Mr. Jones' physician authorized the new prescription. The pharmacist also explained to Mr. Jones the benefit of taking his medications, stating, "Mr. Jones, it is very important that you take both of these medications every day as they can lower your risk of having another stroke." In the case of Mr. Jones, he has suffered a consequence of medication non-adherence, a stroke. His first stroke may have been prevented if non-adherence was addressed sooner. Now, it is important to focus on preventing another stroke or other cardiovascular events.

The American Heart Association states that the "No.1 problem in treating illness today is patients' failure to take prescription medications correctly, regardless of patient age."[2] As part of the first step in embracing drug therapy management in the State of Maryland, pharmacists are working to improve adherence. There is no benefit from a medication if it is not taken. Optimizing adherence in your community setting can be implemented with expectations of better care for your customers, increased revenue for the pharmacy and improved customer loyalty.

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AND THE LAW

By Kenneth R. Baker, B.S. Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

WHAT DO THEY THINK WE ARE?

I recently had a conversation with a friend of mine who told me about a problem he had associated with a prescription medication he was taking. I asked if the pharmacist had explained the medication and potential side effects to him when he picked up the prescription. "Why would a pharmacist do that?" my friend asked. How disappointing it was, more than ten years after OBRA 90 regulations were enacted in almost every state, to hear an intelligent, educated gentleman ask such a question. He knows who pharmacists are, but what is it that he and other patients think we are supposed to do? WHAT do they think we are? Do they think that a pharmacy is nothing more than a "*warehouse for drugs*" and a pharmacist is merely *" a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians"?*[1]

Two decades ago, in the mid 1980s, the legal answers to such questions began to change. In 1986 a Pennsylvania court of appeals decision dramatically contrasted with most legal cases to that time. Before that year, most judges in most states held that pharmacists had no duties that a patient could legally enforce beyond filling the prescription exactly as the physician ordered. Counseling patients on their medication, the courts said, was the duty of the physician, not a pharmacist. Requiring a pharmacist to warn a patient of side effects or how to use drugs might interfere with the patient-physician relationship, they reasoned.

In 1986 a Pennsylvania appellate court decided otherwise. In the case of Riff v. Morgan the court said a pharmacist's legal duty included the duty to "warn the patient or notify the prescribing physician of the obvious inadequacies [in the directions] appearing on the face of the prescription which created a substantial risk of serious harm to the plaintiff."

The case involved "a prescription for a package of 12 Cafergot suppositories, with written instructions thereon to insert one in the rectum every four hours for headache". The Court's opinion indicated that no written material was given and the only directions on the prescription were to insert one every four hours. Mrs. Riff was hospitalized for "*toxicity*", which the jury found was a result of an overdose of the drug. Both the physician and the pharmacy were sued. The physician settled, leaving only the question of the employed pharmacist's liability for failure to warn Mrs. Riff of the potential overdose. The Court pointed out that, according to the experts who testified at the trial, warnings should have been provided to the patient explaining that the "*dose is not to exceed two per attack and in no event should the user administer in excess of five in one week.*"

The attorneys for the pharmacy raised the defense that its pharmacist had no duty to warn Mrs. Riff of the possible effects or overuse of any prescription drug. That, they said, was the duty of the physician. Since the pharmacist had filled the prescription exactly as written, the lawyers argued, the pharmacist's job was over. To this, the Court responded:

[1] Riff v. Morgan, 353 Pa.Super. 21, 508 A.2d 1247 (1986)

The appellant would seem to argue that a pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians. Such is not the case. [The pharmacist has a duty] . . . to warn the patient or notify the prescribing physician of the obvious inadequacies appearing on the face of the prescription which created a substantial risk of serious harm . . ..

The Court added the following explanation:

Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother's keeper. [Emphasis added]

What do they think we are? This judge, at least, realized we have the ability to do more than just pour tablets from one bottle to another. We are not mere clerks – we are the final link in the patient safety net. We cannot warn of all side effects and cannot catch every prescriber error, but we can warn of the common, severe side effects and we can catch some prescriber errors. Sometimes, I think, I wish the public understood what we are and what we can do. But then . . .

Last month my wife and I were out of town and she needed a prescription filled. I took her new prescription to a pharmacy where I knew no one and no one knew that I was a pharmacist. The pharmacy was not busy. I handed over the prescription to a technician (according to her name badge) and was told it would only take a few minutes. She was very pleasant and she was correct – it took only a few minutes for my wife's name to be called. Her prescription was ready.

When I originally gave the tech the prescription, I was not asked if my wife was allergic to anything or what other medications she takes. When I picked up the prescription I was handed a HIPAA notice. The technician smiled and asked, "Do you have any questions?" When I did not immediately ask any question, the technician turn to go back to the counter.

I said, "Is that it?" "Aren't you supposed to counsel me about how to take the medicine or what side effects my wife might expect?" The pharmacist looked up from behind the back counter but did not move or say anything. The technician turned back around and said, with a very pleasant smile, "I asked if you had any questions." And that was it. I let it drop and so did she. In her mind and, I presume, in the pharmacist's mind, they had made an "offer to counsel". According to their procedures they had met the legal requirement of the law.

I walked away sadly thinking that I could have gotten the same degree of pharmaceutical care through the Internet. Perhaps the first question asked in this article is wrong. Perhaps the question should be, "What do WE THINK WE ARE?"

©Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Continuing Education for Pharmacists

Volume XXI, No. 4

Patient Counseling: Smallpox: Part 1, The Disease

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this two-part lesson series is to present information about smallpox and the smallpox vaccine as well as other means of prevention, and to answer questions about the disease and safety issues concerning vaccination.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge about the reasons for current interest in smallpox and the smallpox vaccine;
2. identify specific points of historical interest about smallpox and its eradication;
3. recognize the etiology and pathogenesis, transmission, symptoms and prognosis of smallpox; and
4. demonstrate an understanding of appropriate responses to the public's concerns about smallpox.

This lesson is provided by an educational grant from

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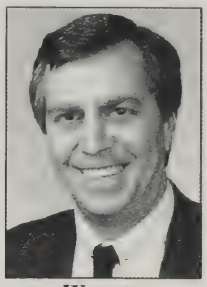

Wuest

"*Smallpox is now a disease of historical interest only, its eradication having been certified by the World Health Assembly on May 8, 1980.*" This profound statement, quoted from a modern textbook of infectious diseases, summarizes the current thought. The disease is no longer discussed in professional curricula, except for its historical relevance. Older pharmacists may remember being vaccinated as a child, or recall the stiff plastic shield taped over the vaccination site to protect the ensuing scab. Most individuals born within the past 30 years have never been vaccinated against smallpox or even seen packages of smallpox vaccine.

In the aftermath of the events of September and October 2001, there is concern that the virus that causes smallpox might be used against this nation, or even worldwide, as an agent of bioterrorism. For this reason, the U.S. government is taking precautions to deal with a smallpox outbreak, and mobilizing health resources to increase professional and public awareness. Part of the emphasis on strengthened homeland security efforts is to also provide protection via vaccination to all Americans against an outbreak of this highly contagious virus.

Smallpox could represent a grave threat to civilian populations if it were used as a biological weapon. The infection has historically been feared as one of the most serious of all pestilential diseases. It was physically disfiguring; it bore a 30 percent case-fatality rate; and some survivors were left blind. Moreover, the disease is communicable and there is still no treatment. If such an attack occurs, the period of time between release of aerosolized smallpox virus and diagnosis of the first cases would likely be as long as two weeks because the average incubation period is 12 to 14 days. Since routine vaccination throughout the U.S. ended in 1972 and the population is highly susceptible and mobile, smallpox could spread rapidly and widely, and probably without detection, throughout this country and the world.

History: Can It Be Repeated?

Historians believe that smallpox (variola) emerged thousands of years ago. The first solid evidence of the contagion in the ancient world is provided from mummified remains of the eighteenth Egyptian dynasty (1580-1350 BC). A written description of the disease, however, was not provided until it appeared in a fourth century AD Chinese text. The name *variola* was first used in the sixth century and is a derivative of the Latin term *varius*, meaning spotted, or *varus*, meaning pimple. The name *smallpox* was first used in fifteenth-century Europe to distinguish variola from the great pox (syphilis).

Smallpox is reported to have first been used as a biological weapon during the French and Indian War (1754-1767). British

forces in North America distributed blankets that had been used to cover smallpox patients to American Indians with the intent of initiating outbreaks among them. Epidemics killed more than 50 percent of some affected tribes.

With Edward Jenner's demonstration in 1796 that an infection caused by cowpox could protect against smallpox, the practice of cowpox inoculation (i.e., vaccination) became accepted worldwide and the potential threat of using smallpox as a bioweapon was greatly diminished. In the early 1950s, there were an estimated 50 million cases of smallpox in the world each year. By 1966, the number had dropped to 10 to 15 million after the disease had been eliminated in 80 percent of the world because of vaccination.

The last confirmed case of smallpox in the U.S. was reported in Texas in 1949. An intensified global campaign was initiated in 1966 under the supervision of the World Health Organization (WHO). The campaign succeeded in eradicating smallpox in 1977. The last indigenous (naturally acquired) case of smallpox occurred in Merka, Somalia in October 1977. Since then, a limited outbreak was caused by a laboratory accident in 1978 in Birmingham, England, killing one person. The WHO officially certified the global eradication of smallpox in May 1980.

The WHO recommended that all laboratories destroy their stocks of smallpox virus or transfer them to one of two WHO reference laboratories – the Institute of Virus Preparations in Moscow, Russia, or the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. All countries were believed to have complied with this request. The WHO later recommended that all virus stocks be destroyed by June 1999. Meanwhile, in 1998, possible research uses for the virus were suggested. There were questions of medical interest that might be addressed if the virus were to be retained and studied. Complete destruction scheduled for the following year was, therefore, halted.

Today, smallpox is classified as a Category A agent by CDC. Category A agents are those that pose the greatest potential threat for adverse public health, and have a moderate to high potential for large-scale dissemination. Other Category A agents include anthrax, plague, botulism, tularemia, and viral hemorrhagic fever. If smallpox were to be deliberately reintroduced as an epidemic disease, it would be an international crime of unprecedented proportions. Releasing the virus in aerosolized form would disseminate it widely, given the considerable stability of the virus in an aerosol and the likelihood that the infectious dose is extremely small.

Microbiology

Smallpox is a DNA virus belonging to the genus *Orthopoxvirus*, family Poxviridae. Orthopoxviruses are large and complex. The virion is a brick-shaped structure with a double-stranded DNA genome. They differ from most other DNA viruses in that they replicate in the cell cytoplasm rather than in its nucleus. Doing so produces a variety of proteins not produced by other DNA viruses (e.g., herpes virus). Two other members of the genus *Orthopoxvirus* are cowpox (vaccinia) and monkeypox. Both are also human pathogens that produce cutaneous lesions. However, smallpox is readily transmitted from person to person. Monkeypox infects primates, anteaters, and squirrels and is found only in tropical rain forest areas of central and western Africa. Cowpox has many natural hosts, including cows, rodents, and cats, and is found only in Europe and adjacent areas of the former Soviet Union.

Epidemiology

In laboratory experiments, 90 percent of aerosolized smallpox virus has been shown to be inactivated within 24 hours. In the presence of ultraviolet (UV) light, this percentage is even greater. Virus contained in lesion scales (i.e., scabs) is more durable. At 95° F and 65 percent relative humidity, the virus has persisted for three weeks. At 79° F, the virus has been confirmed to survive for eight weeks at high relative humidity and 12 weeks at a relative humidity less than 10 percent. The occurrence of smallpox was greatest in winter and early spring. All poxviruses are rapidly inactivated by exposure to UV light, and chemical disinfectants such as bleach or Lysol.

Smallpox virus was spread by contact with infected persons. Direct and fairly prolonged face-to-face contact (i.e., within six to seven feet) was generally required. Infected persons exhaled small droplets of fluid that transported the virus to the nose or mouth of close contacts. Although indirect contact was less likely to transmit the virus, infection could still occur via fine-particle aerosols or inanimate objects carrying the virus. Contaminated clothing or bed linens, for example, could spread the virus. Humans are the only known reservoir of the virus and there are no insect vectors.

The rapid spread of smallpox was generally slower than for other diseases such as measles or chickenpox. Victims usually spread smallpox to family members and friends. Large outbreaks in schools and industry, for example, were uncommon. The epidemiology can be explained, in part, by the fact that transmission of the virus did not begin until onset of rash. Many patients were confined to bed by this time because of the presence of high fever, malaise, and other symptoms.

Historically, the distribution of cases by age correlated best with the degree of smallpox susceptibility in the population. Children developed the largest number of infections mainly because vaccinated adults were protected by immunity or, in part, by previous smallpox infection. In regions where vaccination or smallpox was rare, the distribution of cases by age resembled the age distribution of the population. It is anticipated that the age distribution pattern of cases in the U.S. today

would be the same if a smallpox epidemic were to occur now, since vaccination of the population ceased three decades ago and, according to CDC, the nation's immunity has since waned substantially.

Pathogenesis and Clinical Presentation

Infection occurred, as stated above, after the virus came into contact with the oropharyngeal or respiratory mucosa. The infectious dose was unknown but believed to be as little as only a few virions. The virus migrated to and multiplied in regional lymph nodes. Asymptomatic viremia set in on the third or fourth day. This was followed by further multiplication of the virus in the spleen, bone marrow, and the lymphatics. By about the eighth day, viremia was accompanied by fever and toxemia. The virus localized in small blood vessels supplying the skin and the oral and pharyngeal mucosa where it subsequently infected adjacent cells.

During the incubation period of smallpox (12 to 14 days; range, seven to 17 days) there was no evidence of viral shedding. Patients felt healthy and could not infect other people.

After the incubation period, the victim experienced sudden onset of high fever (101°-104° F), malaise, headache, and prostration – symptoms resembling influenza. Some experienced severe backache and less often, abdominal pain, vomiting, and delirium. The victim usually appeared quite ill. This period usually lasted two to four days, after which the high fever abated and the patient felt somewhat better. Fever usually returned by the seventh or eighth day of the illness and remained high until crusts formed over all the lesions. Lesions in the mouth and pharynx ulcerated quickly due to the absence of a stratum corneum, which released large quantities of virus into the saliva. The level of virus in saliva was highest during the first week of illness, corresponding to the period when patients were most infectious.

A maculopapular rash appeared on the mucosa of the mouth and pharynx, face, and forearms, then spread to the trunk and legs. The rash usually appeared over the entire body within 24 hours. The rash became vesicular within one to two days, and later, pustular. Pustules were characteristic: sharply raised, typically round, tense, and firm to the touch. They were deeply embedded in the dermis and felt like a small bead in the skin. Some individuals described the bumps as feeling like "BBs" under the skin. Fluid began to be absorbed slowly from the pustules, and crusting began on about the eighth or ninth day of the rash. By day 14, most of the lesions were scabbed over. As the patient began to recover, the scabs began to fall off, leaving depigmented skin and pitted scarring characteristic of the infection. Scars were most common on the face, and formed due to destruction of sebaceous glands followed by fibrosis and shrinking of granulation tissue.

Other than lesions in the skin and mucous membranes, and reticulum cell hyperplasia, other organs did not appear to be involved in the majority of victims until near the time of death. Secondary bacterial infection was uncommon. Respiratory complications (e.g., bronchitis, pneumonitis, or pneumonia) developed in some victims about the eighth day of the illness. Encephalitis occurred occasionally. Death, which occurred between the tenth and sixteenth days of the illness, was blamed on toxemia associated with circulating immune complexes and variola antigens.

By the sixth day of rash, neutralizing antibodies could be detected. In some cases these remained in high concentration for many years. Hemagglutinin-inhibiting antibodies were present by about the sixth day of rash, or about 21 days into infection. Complement-fixing antibodies appeared approximately two days later. Hemagglutinin-inhibiting antibodies declined to low levels within five years; complement-fixing antibodies were rarely detected after six months.

Table 1
Classic Presentation of Chickenpox

- Lack of or mild premonitory (i.e., prodromal) symptoms of disease
- Lesions are superficial vesicles; ("dewdrop on a rose petal")
- Lesions appear in crops; on any one part of the body where there are lesions in different stages (papules, vesicles, crusts)
- Greatest concentration of lesions on the trunk, fewest lesions on face and legs although these areas may be involved
- First lesions appear on the face or trunk
- Patients rarely "deathly ill"
- Rapid evolution; lesions evolve from macules to papules to vesicles to crusts quickly (<24 hours)
- Palms and soles rarely involved
- 50 to 80 percent of persons in various studies recall an exposure to chickenpox or shingles 10-21 days before rash onset

Variola Types. Two main clinical forms of smallpox have been described, major and minor. *Variola major,* the severe form of smallpox, was distinguished by a more extensive rash and higher fever. It was also the most common form of smallpox. There were four subtypes of variola major: ordinary (the most frequent), modified (mild and occurring in previously vaccinated persons), hemorrhagic, and malignant. As stated earlier, variola major has a case-fatality rate of about 30 percent; however, hemorrhagic and malignant smallpox were most often fatal.

Hemorrhagic smallpox occurred among all ages. Both sexes were susceptible, but pregnant women appeared to be especially prone. Illness was characterized by a shorter incubation period and severely prostrating early illness. A high fever with intense head, back, and abdominal pain were present. Soon, the skin appeared dusky (darker than usual) and erythema

Table 2
Conditions Possibly Confused with Smallpox

Condition	Clinical Clues
Chickenpox (primary infection with varicella-zoster virus)	• Most common in children <10 years; children usually do not have a viral prodrome
Disseminated herpes zoster	• Immunocompromised or elderly persons; rash looks like varicella
Impetigo *Streptococcus pyogenes* *Staphylococcus aureus*	• Honey-colored crusted plaques with blisters are classic, but they begin as vesicles; regional, not disseminated rash; patients generally not ill
Contact dermatitis	• Itching; contact with possible allergens; rash often localized in pattern suggesting external contact
Erythema multiforme minor	• Target "bull's eye" lesions; often follows recurrent herpes simplex virus infections; may involve hands and feet (including palms and soles)
Erythema multiform (including Stevens Johnson Syndrome)	• Major form involves mucous membranes and conjunctivae; may be target lesions or vesicles
Disseminated herpes simplex	• Lesions indistinguishable from varicella; immunocompromised host
Scabies; insect bites (including fleas)	• Itching is a major symptom; patient is not febrile and is otherwise well
Molluscum contagiosum	• May disseminate in immunocompromised persons

www.cdc.gov/nip/smallpox; www.bt.cdc.gov/EmContact/index.asp

developed. This was followed by petechiae (tiny, localized blood spots) and generalized hemorrhaging into the affected skin and mucous membranes. Death was common by the fifth or sixth day after onset of rash.

In the malignant form of the disease, initial symptoms and constitutional elements were similar to those of hemorrhagic smallpox. Lesions developed slowly and remained soft, flattened, and velvety to the touch. They did not proceed to the pustular stage. If the patient survived (and this was unlikely), the lesions disappeared gradually without forming scabs. Large areas of epidermis peeled off in severe cases.

Variola minor was a less severe form of smallpox in which patients experienced fewer constitutional symptoms. The rash was sparse. In individuals with residual immunity from earlier vaccination, a milder form of disease sometimes developed. In these individuals, the rash was normally atypical and more scant, and evolution of the lesions more rapid.

Detection

Today, appearance of a single suspected case of smallpox must be treated as a potential international health emergency. The victim should be brought to the attention of local health authorities at once.

A victim of smallpox would bear a characteristic rash that is described as centrifugal (defined below) in distribution, i.e., most dense on the face and extremities. Lesions would appear over a one- to two-day period. On any given part of the body at any point, they would be in the same stage of development.

This contrasts with chickenpox (varicella), the disease most often confused with smallpox and an infection of children that is seldom lethal (Table 1). In chickenpox, new lesions appear in centripetal distribution (i.e., on the trunk) and in batches every few days. Lesions at different stages of maturation (i.e., vesicles, pustules, and scabs) can be found in adjacent areas of skin. The lesions are also more superficial than smallpox and are never found on the palms and soles.

If the terms centrifugal and centripetal are confusing, consider the following explanation from Physics 101. Imagine an individual lying on his back with a collection of pebbles on his midsection. If that person were spun around briskly in a horizontal plane, *centrifugal* force would impel the pebbles outward toward his face and legs. That would be the distribution of lesions in smallpox – on the face and legs. *Centripetal* force, on the other hand, is the force necessary to keep a rotating object toward the center of rotation. Tie one of those pebbles onto the end of a string and whirl it around. While in motion, centripetal force acts on the pebble pushing inward from the outside. The distribution of chickenpox lesions occurs in the midsection (i.e., toward the middle, the trunk).

Smallpox infection can be confirmed by electron microscopic examination of vesicular or pustular fluid or scabs. A careful history and clinical picture readily differentiates cowpox and smallpox. Also, cowpox has not been found in the U.S. Smallpox and monkeypox virions may be indistinguishable, but like cowpox, monkeypox is not found in the U.S. Table 2 lists a sampling of medical conditions that might be confused with smallpox.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Smallpox: Part 1, The Disease". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 4/15/06. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-03-004-H01.

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1. All of the following statements about smallpox infections are true EXCEPT:
   a. they were physically disfiguring.
   b. they bore a 30 percent case-fatality rate.
   c. some survivors were left blind.
   d. they were successfully treated with formaldehyde soaks.

2. Routine vaccinations against smallpox throughout the U.S. ended in:
   a. 1952.
   b. 1962.
   c. 1972.
   d. 1982.

3. Smallpox is reported to first have been used as a biological weapon during the:
   a. French and Indian War.
   b. Revolutionary War.
   c. Civil War.
   d. World War II.

4. The WHO officially certified the global eradication of smallpox in:
   a. 1975.
   b. 1980.
   c. 1985.
   d. 1990.

5. Smallpox viruses differ from most other DNA viruses in that they:
   a. are small and not complex.
   b. replicate in the cell cytoplasm rather than its nucleus.
   c. have a single-stranded DNA genome.
   d. have a virion that is circular in shape.

6. In laboratory experiments, the percentage of inactivation of aerosolized smallpox viruses was increased by the presence of:
   a. alcohol.
   b. gentian violet.
   c. phenol.
   d. ultraviolet light.

7. The incubation period of smallpox is:
   a. three to five days; range two to seven days.
   b. six to 10 days; range eight to 12 days.
   c. 12 to 14 days; range seven to 17 days.
   d. 15 to 18 days; range 13 to 21 days.

8. When smallpox infection occurred, the most common form was described as:
   a. varicella major.
   b. varicella minor.
   c. variola major.
   d. variola minor.

9. A patient with a skin lesion described as being a "dewdrop on a rose petal" is most likely to be infected with:
   a. chickenpox.
   b. smallpox.

10. A victim of smallpox can be differentiated from one with chickenpox because the smallpox rash is characteristically described as:
   a. most dense on the face and extremities (centrifugal).
   b. most dense on the trunk of the body (centripetal).

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MARYLAND
Pharmacist
VOLUME 80 NO. 4

President's Message
"Visibility, Communication, and Influence"

Drug Therapy Management Series
"Part 2: Focus on Smoking Cessation"

RX and the Law
"A Short Course on Evidence for Pharmacists"

Continuing Education
Patient Counseling:
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OCT./NOV./DEC 2004

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Maryland Pharmacist

The Official Publication of the Maryland Pharmacists Association

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In Remembrance

Nathan I Gruz, long time Executive Director of the Maryland Pharmacist Association, died of complications from a stroke Saturday, October 9, 2004, at the age of 84.

Mr. Gruz held the joint positions of Maryland Pharmacists Association (MPhA) and Baltimore Metropolitan Pharmaceutical Association (BMPA) Executive Secretary, later changed to Executive Director, from 1961 to 1977, succeeding Joseph Cohen. Upon retirement Nate, as he was known, was named Executive Director Emeritus of the MPhA.

Mr. Gruz, a 1936 graduate of the Baltimore City College High School, earned his degree in pharmacy at the University of Maryland School of Pharmacy and later received a master's degree in science from what is now Towson University. He held the position of President of the University of Maryland School of Pharmacy Alumni Association in 1968-69.

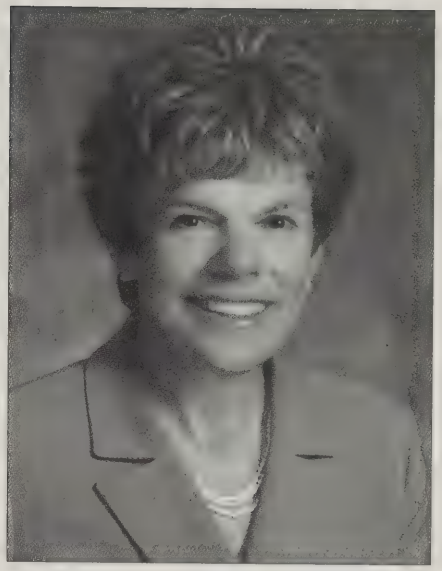
Perhaps his greatest talent was his writing ability, which was reflected in his articles in the *Maryland Pharmacist*, the Journal of the Association. He was instrumental in resurrecting the MPhA *Newsletter* in 1976. During his tenure as a leader of the MPhA, he helped to guide pharmacists through problems and to delay implementation of legislative action, which could be harmful to the profession. He pressed for the legislation, which required continuing education credits as a pre-requisite for license renewal, one of the many ways he helped to add to the stature of pharmacists and pharmacy. Nate was so regular a participant in Annapolis during the General Assembly sessions that some thought he was a voting member.

Prior to his career in pharmacy association work, he had served as an Army medical supply officer in the Philippines during World War II, then as a supply officer with the United Nations Relief and Rehabilitation Administration in Shanghai, China. Nathan was a Lieutenant Colonel in the Army Reserves. He was owner of the Brunswick Pharmacy on Wilkens Avenue before coming to the MPhA, and finished his pharmacy career at the Stella Maris Hospice Pharmacy. Even after his tenure with the Association he was a regular at Board of Pharmacy meetings, regularly offering his advice and voicing his opinion on behalf of pharmacists.

Nathan Gruz is survived by his wife of 58 years, the former Ursula Stein, a son, two daughters and two grandsons.

President's Message

The responsibility of serving as the MPhA president has become increasingly evident over the past few months as Montgomery County Council has proposed to ignore federal laws that prohibit prescription drug importation. I have been asked to speak at press conferences and on television, and I have provided editorial letters to newspapers in support of access to medications in ways which assure product safety and coordination of care. I am not fearful about speaking in public, because I face classes of students regularly. I am most concerned that I represent pharmacy and pharmacists in Maryland in the most appropriate way, given our diverse practice settings and interests.



Cynthia J. Boyle, Pharm.D.

"Visibility, Communication, and Influence"

For my term of office, I serve as your spokesperson and have visibility. It occurs to me that a pharmacist member has much more significant visibility in a pharmacy than my episodic media events. This became very obvious as I attended the funeral for one of our preceptors Dennis Rosenbloom. Patients, allied health workers, and co-workers all spoke to his humanity, his expertise, his mentorship, his selflessness, and his humor, but his greatest gift seemed to be his ability to communicate.

Joan Lusby, a physician assistant at McDaniel College, explained that Dennis shared his knowledge with patients, and filled them with hope. He instilled self-confidence in his young part-time employees at the Rexall Pharmacy so that they would strive to continue their education. He taught thousands of clients at the health department in the diabetic clinic, not to mention dozens and dozens of student pharmacists. He communicated absolute respect to patients, irregardless of their circumstances. He was a role model, a resource, a listener, and a gifted practitioner.

If this one pharmacist influenced so many people through his visibility and communication, how much influence can we exert collectively as an organization on behalf of our profession and public health. Sometimes we just need to step back to appreciate our key role in helping patients use medications appropriately and to make appropriate health choices. As one example, how many individuals, or groups of individuals, can you help to stop smoking to improve their health? Set a goal. Document and share your success. Your professional satisfaction and our profession depend on your accessibility, visibility, and communication; and there is no better time than October and American Pharmacy Month to exert your influence.

This is the second of a four-part series on Drug Therapy Management. This series is intended to provide the community pharmacist with practical tips for improving care, generating revenue and increasing customer satisfaction.

"Drug Therapy Management Series: Part II: Focus on Smoking Cessation"

Authors: Eileen Ripple[a] and Catherine E. Cooke, PharmD, BCPS[a,b]
[a]University of Maryland School of Pharmacy, [b]Pfizer, Inc.

Despite warnings that tobacco use is the primary known preventable cause of disability and death in the United States, about 25% of the population continues to smoke. At least 70% of those who currently smoke want to stop and have attempted to quit at least once. Unfortunately, only 2% are successful in achieving smoking cessation without any outside help.[1] This demonstrates the need for pharmacists and pharmacy technicians to assist smokers with quitting. By getting involved, you can expect healthier and more satisfied customers, increased revenue from smoking cessation products and increased professional satisfaction.

People who smoke are not only at increased risk of lung cancer, but increased risk of cardiovascular disease. Tobacco use increases the risk for myocardial infarction, stroke, peripheral vascular disease, and aortic aneurysm.[2] About 87% of lung cancer cases are thought to be the result of smoking or passive exposure to tobacco smoke and there will be an estimated 160,440 deaths from lung cancer this year.[3] Chronic obstructive pulmonary disease and cardiovascular disease are among other leading causes of death that can be decreased through smoking cessation. Many patients feel like Mr. Smith (see Case Example). However, it is never too late to encourage quitting. Even after smoking for 30 years, Mr. Smith's risk of heart disease can be decreased if he quits smoking.

November is Smoking Cessation Month and all pharmacists and technicians are encouraged to become involved in smoking cessation activities. What can you do? There are several steps you can implement to assist patients with quitting smoking. (See Table 1) The first step is to *ask* each patient with every prescription if he/she smokes. It is important to document smoking status as smoking has the potential to alter the response to different medications. Smoking cigarettes may affect the effectiveness of analgesics, anxiolytics, antidepressants, antipsychotics, propranolol, theophylline, heparin and insulin.[4] Hydrocarbons

Case Example:
Mr. Smith is a regular customer at your pharmacy for over 5 years. His only medical problem has been hypertension, for which he takes hydrochlorothiazide (HCTZ) 25mg daily. He comes every month to get his HCTZ refilled and often brings his grandson with him. Today, he is alone and says to you, "my doctor told me I had better quit smoking. I've been smoking for over 30 years. Why should I quit now? Plus, I tried to quit a few times cold-turkey and I couldn't even make it though one day."
What advice do you have for Mr. Smith?

Table 1 – Strategies to improve smoking cessation

1. *Ask* each patient with every new prescription if he/she smokes
2. *Document* smoking status in patient's record
3. *Advise* smokers to quit
4. *Assess* the individual situation and patient's readiness to quit
5. *Assist* with the smoking cessation process (e.g., quit date, behavioral counseling, smoking cessation products)
6. *Arrange* a follow-up meeting during the first week of quitting and then again in the first month

contained in cigarette smoke can induce liver enzymes to make certain drugs less effective. While a patient smokes, he/she may need a higher dose of these medications and more importantly, then he/she quits, the dose may need to be lowered to prevent toxicity.

After you have determined that the person smokes and *documented* this information in their record, *advise* the smoker to quit. It is important to be understanding and empathetic. You must then *assess* the individual situation and the patient's readiness to quit. If the patient is not yet ready to quit, any attempts will unlikely be successful. At this point, the best interventions are to continue to advise the smoker to quit and encourage discussion about feelings that will move your patient from contemplation about quitting smoking to action. For some people, like Mr. Smith, there may be other factors besides health benefits that would encourage the patient to quit. The pharmacist knows that Mr. Smith does not want his grandson to smoke so the pharmacist might say to Mr. Smith, "You told me that you don't want your grandson to smoke and yet he sees you smoking." Helping Mr. Smith to realize that his actions (i.e. smoking in front of his grandson) are not in line with his goals (i.e., he does not want his grandson to smoke) may move him to action.

If the patient is ready to quit, the next step is to *assist* with the process. This can include a discussion about avoiding smoking triggers (e.g., smoking after finished eating dinner), the importance of changing routines (e.g., scrambling the patient's routine to decrease associations of smoking with daily habits), coping strategies (e.g., personally chosen distractions the patient can try when he/she has an urge to smoke) social support, and medication counseling. Pharmacists should recommend the use of FDA-approved medications for smoking cessation. This includes OTC nicotine patch, gum, inhaler and spray as well as prescription bupropion, sustained-release. For maximum benefit from the product recommended, it is essential that you counsel the patient on the correct use of each of these medications. (See prescribing information and patient instructions packaged with the product). It is also important to address patient-specific concerns. For example, weight gain can be a major concern for patients wanting to quit. Patients may use food as a distraction from smoking. It is important to encourage patients to keep healthy snacks around such as grapes, carrots or celery sticks.

A quit date should be set at least two or three days away, but no more than two weeks away. It is important to *arrange* a follow-up meeting during the first week of quitting and then again in the first month.[5] Evidence that pharmacists can make a difference was documented in the journal *Addiction* as 14.3% of smokers attempting to quit while in a pharmacist intervention group continued to be abstinent at 12 months, as opposed to only 2.7% who remained abstinent at 12 months without any intervention.[6]

An example of a pharmacist successfully involved with smoking cessation activities right here in Maryland is Dr. Arnold 'Skip' Amass. As many of you heard during MPhA's 2004 Awards Banquet, Dr. Amass showed how a pharmacist could realistically make a difference with smoking cessation. He was an integral part of the Smoking Cessation Team at the National Security Agency and conducted smoking cessation classes with success rates averaging 45-55% after one year.[7] Because he was employed with the military, Dr. Amass was in a unique situation that provided him, without effort, the medical personnel and funding necessary. In setting up a community pharmacy smoking cessation program, there are resources that can provide you with the tools you need to help your patients quit. (See Table 2)

Table 2 – Resources for Smoking Cessation Activities in Community Pharmacy

- National Center For Chronic Disease Prevention and Health Promotion at http://www.cdc.gov/tobacco/edumat.htm
- *Treating Tobacco Use and Dependence: A Public Health Service Clinical Practice Guideline* at http://www.ahrq.gov/path/tobacco.htm
- You Can Quit Smoking! at http://www.surgeongeneral.gov/tobacco/smconsumr.pdf
- Medline Plus- Smoking Cessation at http://www.smokefree.gov/
- American Lung Association: Web-Based Smoking Cessation Support at www.lungusa.org
- American Cancer Society at 1-800-ACS-2345 or visit www.cancer.org
- UCSF RX for Change at http://rxforchange.ucsf.edu/

In addition to one-on-one activities for smoking cessation in your pharmacy, there are also group programs that you can offer. Dr. Amass continues to be part of a program that teaches health care professionals how to conduct these group programs. For more information, contact Dr. Amass at arnoldams@adelphia.net.

Providing assistance with smoking cessation in your pharmacy will improve your patients' health, and will benefit the pharmacy as well. Patients are likely to purchase smoking cessation products at the same location where they are recommended, which can increase revenue for the pharmacy. Furthermore, the pharmacy will benefit from publicizing the opportunity for smoking cessation support. As some patients are actively looking for assistance with their quest to quit, this is an ideal way for pharmacies to gain new customers who would not otherwise patronize the store. Two major obstacles patients complain of are most cessation clinics are impersonal and hours are not convenient. Community pharmacists are in the position to offer individualized support at a time suitable to the patient as nearly every pharmacy has longer hours than physician offices. Mr. Smith received advice from his physician to quit, but that was all. Using the tools and resources provided above, the pharmacist is able to assist Mr. Jones with quitting smoking.

Pharmacists must actively seek out anyone who smokes and attempt to initiate the smoking cessation process. Pharmacists can publicize that they are available to advise, assess, and assist with quitting. The most successful interventions appear to be those characterized by personalized advice and assistance, repeated in different forms over the longest feasible period of time.[8] The public desire for assistance with quitting smoking is in great demand, and community pharmacists are in a wonderful position to provide these services. By providing support and believing in the patient, you can make a difference. As part of the second step in embracing drug therapy management in the State of Maryland, pharmacists are working to help patients quit smoking. Smoking cessation activities in your community setting can be implemented with expectations of better care for your customers, increased revenue for the pharmacy and improved customer loyalty.

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[4] University of Minnesota, Division of Periodontology: Smoking and Drug Interactions. [electronic database] URL: http://www1.umn.edu/perio/tobacco/smoke-druginteract.html. Accessed September 2004.

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[6] Maguire TA, McElnay JC, Drummond A. A Randomized Controlled Trial of a Smoking Cessation Intervention based in Community Pharmacies. *Addiction*. 2001;96(2):325-31.

[7] Personal communication, August 2004, Dr. Arnold "Skip" Amass, arnoldams@adelphia.net

[8] McElnay JC, Maguire TA, Drummond A, et al. Smoking Cessation: The Contribution of Community Pharmacy. *Disease Management & Health Outcomes*. 2000;8(3):147- 58.

The Benefits of Membership

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Pharmacy and Healthcare Issues on both a regulatory and legislative level. The unique position of MPhA enables the Association to more effectively assert the position of its members than do national or specialty associations.

The MPhA's Executive Director attends the monthly meetings of the Board of Pharmacy, and participates on behalf of MPhA on various committees consisting of pharmacists and other health care professionals.

Regulations which affect pharmacists are influenced through the actions of MPhA and its Legislative Committee.

A Toll-free Hotline—

Members can call 800-833-7587 for answers to practice-related questions. Due to the very nature of a professional association, the resources available to MPhA are greater than those available to individual practitioners. If we cannot answer the question or concern based on MPhA's resources, the MPhA staff will try to find the information needed by the member.

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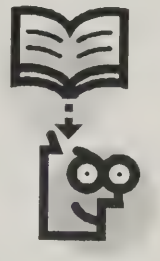

The Mid-Year Meeting will be held January 30, 2005 at the Sheraton Columbia Hotel in Maryland, and the Annual Convention is June 11-14, 2005 at the Clarion Resort Fontainebleau Hotel in Ocean City, Maryland. Convention attendees have plenty of time to relax and enjoy, and can earn approximately 20 continuing education credits toward their licensure renewal requirement.

Our business meetings are scheduled to give everyone a chance to participate in the Association's policy decisions.

Publications—

The "*Maryland Pharmacist* " journal and the "*MPhA Pharmacy News*" newsletter is published quarterly and monthly, respectively. In the recent past, these publications have dealt with issues which include collaborative practice, medication errors, confidentiality laws, pharmacists' workloads, the shortage of pharmacists, and the HIPAA regulations. There is a CE in each edition of the journal.

Pharmacy Laws and Regulations—

A copyrighted publication of the Pharmacy laws and regulations governing the practice of pharmacy in Maryland—which is updated annually—is available to members at a discounted price.

The revised lawbook contains the pharmacy laws to ensure compliance, provide information pertaining to prescribers as they impact on dispensing by pharmacists, on laws related to confidentiality of medical records, and on insurance as it effects pharmacy.

The lawbook also contains a commentary that is provided in layman's language explaining Title 12, and other statutes and regulations. It is also used as a teaching tool at the University of Maryland, School of Pharmacy for the students in the Pharm.D. program.

All parts of the revisions passed during the end of the previous year's legislative session will be included in

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Networking—
Different locations and different practice settings, hands-on and through other State Pharmacy Associations—members have the unique opportunity to meet and develop professional relationships with practitioners in all types of health care settings. By planning and acting together, pharmacists can use a combination of knowledge and experience to benefit not only the profession, but also patients.

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If you have any questions about these member benefits please feel free to call the MPhA office at 410-727-0746 or e-mail us at hschiff@maryland pharmacist.org.

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Rx AND THE LAW

By Kenneth R. Baker, B.S.Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

A SHORT COURSE ON EVIDENCE FOR PHARMACISTS

What do you do when the unthinkable happens? Every pharmacist knows they can and do make mistakes. All of us can remember times when we were responsible for a medication error. If we have a good prescription system, we usually can catch the mistake before it reaches the patient. Eventually, if we practice long enough, one of these near misses reaches a patient and it becomes an error and every pharmacists' worst nightmare.

What happens at that point is often a question of luck. The patient may notice the mistake and return the prescription to the pharmacy before any of the drug is taken. The patient may take the medication, but no harm results. For example, a prescription for an otic is mistakenly filled with an ophthalmic form of the drug. A medication error was made, but no one was injured, the patient probably got well and neither the pharmacist or the patient ever knows a mistake was made.[1] Too often, however, the patient does take the incorrect medication and notices the mistake only afterwards. How does the pharmacist handle the situation when a patient returns to the pharmacy alleging that the pharmacy made an error? What evidence does the pharmacist need to preserve? What can be said and what should not be said?

A conversation with a patient may seem very cordial and it may seem that the matter has ended on a good note. Most times the feeling that "everything went well" proves to be correct and the matter is over. Occasionally, however, the patient receives advice from relatives or others and the friendly exchange escalates into a claim and/or a lawsuit. The problem is you can never be certain what the future will hold, so you should document as if there will be a reason to be able to recall exactly what was said and done. Consider a few sample procedures to follow whenever an incident happens that could lead to a professional liability claim.

The first rule is take care of the patient. Whether you or someone in your pharmacy made a mistake, or someone else did, your patient has a potential problem. Usually, the patient is concerned and anxious. There could be worse injuries if treatment is delayed. Find out if the patient took any of the wrong medication or if they missed any prescribed medication. Make certain that they get any necessary medical help. Not only may this mitigate damages caused by the error, more importantly, your patient may need to receive

[1] In a study at Pharmacists Mutual over a three-year study, 2% of all claims filed against pharmacists involved a prescription for an ophthalmic filled with the otic form. Never in the past fifteen years, however has Pharmacist Mutual received a claim for an ophthalmic drop mistakenly given for a prescribed otic.

treatment. Whether or not they need care, is probably not your decision, but the patient's and the prescriber's. Even if there is no apparent injury, you need to call the prescriber so the information can be placed in the patient's file. The Iowa Supreme Court in McClure v. WALGREEN[2] criticized the pharmacy for failing to warn the patient of the potential effects of the error when its employees discovered the mistake and used this failure as one of the bases of additional damages.

Once all emergencies have been handled, try to find the extent of any potential problems by asking questions. Try to discover if the patient actually took any of the erroneous prescription medication. If so, how much and when did they take it? Document the conversations with the patient or the caregiver, as you may not be able to recall all of the facts later. If what was said is ever needed, remember that any trial or deposition may be two years, three years or longer in the future. You will need and under court rules can use your notes to refresh your recollection at that time. All documentation must be truthful and accurate as your creditability will be on trial as well as the case. If possible, have a witness to the conversation who can initial the notes. In addition, you should retrieve any incorrect prescription to prevent any additional harm, but do not destroy it. Count the tablets and save the bottle. Treat this as evidence by placing it in an envelope and sealing it with your initials on the closure.

The best place to document is on the back of the prescription or on paper stapled to the prescription or in a file folder kept for this particular incident. Wherever you document, the notes must be easily found and retrieved later. Notes in the computer can be lost and hand written notes are more easily authenticated. Pharmacists Mutual has a documentation journal available for this purpose. You can get one or more from your Pharmacists Mutual representative or by calling the company and asking for the "*Pharmacists Journal*".

If you make an obvious error, you may say, "I made a mistake, I am sorry." You may not, however, admit liability or offer to pay money or to settle the case using your own money, as one pharmacist did under pressure from an angry customer. Admitting liability is more than saying I made a mistake. A mistake, such as putting the wrong drug in the bottle, is a fact question. Admitting liability, such as saying: "I caused your injuries", is a legal statement. Not only would admitting liability be a possible violation of the conditions in your insurance policy, but would also probably be beyond your knowledge. The patient may have other conditions or other incidents of which you are not aware.

If the error is not obvious to you or if you think you are not responsible for the mistake, you should not argue the point with the patient, but you can express sympathy for the patient. You can always say, "I'm sorry you feel bad". When any mistake is made that could result in a claim, immediately report it to your insurance company. Your policy may have penalties for not reporting promptly. Finally, train your staff how to react if the "unthinkable" happens. A question like "Why is this tablet a different color" should be a "pharmacist only question". The pharmacist should treat every such question as an error unless and until the opposite is PROVED.

©Kenneth R. Baker is Senior Vice President, General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

[2] Walgreen v. McClure, 613 NW 2d 225, Supreme Court of Iowa. (July 6, 2000). The Iowa Court's reasoning in this part of the case can be criticized as inconsistent with the facts, however.

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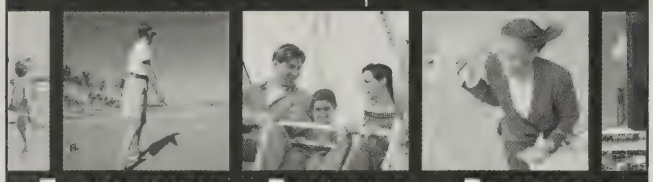

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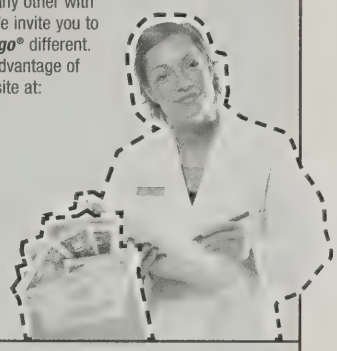

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Maryland Pharmacists Association Opposes Importation

by Howard Schiff, P.D. and Cynthia Boyle, Pharm.D.

The challenge facing many Americans is how to pay for growing lists of medications needed to manage chronic medical conditions. Out of desperation, some have turned to the Internet or foreign countries to obtain imported medications at a lower expense. Unfortunately, these people are placing themselves at increased risk for counterfeit and contaminated medications. Drugs that are imported are not guaranteed to be safe.

Congress enacted the Prescription Drug Marketing Act (PDMA) in 1988 to prevent substandard and counterfeit drugs from entering the United States (U.S.) The PDMA makes it illegal for anyone other than the original manufacturer of a drug to re-import the drug back into the U.S.

The U.S. Food and Drug Administration (FDA) mandates high standards for drugs sold to the American public. Drugs that are imported cannot be assured to meet high standards. Testimony from John Taylor, the Associate Commissioner for Regulatory Affairs at the FDA provides evidence to support this. On May 20, 2004, he stated the findings from inspections conducted at selected American airports on mail shipments of imported foreign drugs. During one inspection, the FDA found that out of a total of 1,153 shipments examined, 1,019 packages (88%) contained drugs unapproved by the FDA; only 16% of these drugs were from Canada. The remaining 84% were from India, Thailand and the Philippines. Similar concerns were found after another inspection. Of the 3,375 imported drug shipments, 69% contained FDA recalled drugs, drugs not meeting storage and shipping requirements to maintain integrity, and controlled substances.

The Maryland Pharmacists Association (MPhA) is against importation and we have been actively engaged in political discussions surrounding this issue. Officers, Board members, Staff, and members at large have been participating in legislative activities to oppose importation. Recently, Cynthia Boyle, our President, wrote a letter to the Washington Post. Her letter to the Editor was published on Thursday, August 26, 2004 on page A22. This letter was written to provide the facts so that the Montgomery County Council and the public could make informed decisions about importation. Excerpts from her letter follow.

Don't Import Prescription Drugs
Washington Post, August 26, 2004
By Cynthia Boyle, Pharm.D.
President, Maryland Pharmacists Association

Allowing imported drugs from Canada, as the Montgomery County Council is considering, is a potentially dangerous decision based on politics and economics rather than on established pharmaceutical best practices [letters, Aug. 7].

The U.S. Food and Drug Administration, which has built the world's safest drug system, has twice been authorized to approve importation if its experts can guarantee the safety of the imported medicines. Under both the Clinton and Bush administrations, the FDA has been unable to provide such safety guarantees. How can one Maryland County do what the FDA cannot?

…the Canadian Internet pharmacies often ship American patients generic substitutions of the medicines they have ordered. When the cost of shipping and handling is added, these medications could have been bought at a local pharmacy for less.

Encouraging patients to bypass local pharmacists and the established safety protocols developed by state pharmacy boards and the FDA threatens patients and the safety of our national drug supply with mislabeled, mishandled, sub-potent or counterfeit drugs.

In addition to the above letter, MPhA has partnered with the FDA to produce, ***"Looks Can Be Deceiving"***. A copy of the brochure can be found by visiting MPhA's web site or by typing in the following link, http://marylandpharmacist.org/pdf/looks.pdf. This document addresses concerns about quality assurance, counterfeit potential, presence of untested substances, risks of unsupervised use, labeling and language issues and lack of information.

Please make your voice heard by contacting your local legislator, because the issue will be prominent in the upcoming General Assembly Session. For listings go to the following website: http://www.loc.gov/global/state/md-gov.html

The following are some of MPhA's "Talking Points Against Importation."

SAFETY: DON'T RISK IT

- The FDA repeatedly has said importing drugs is unsafe. In addition to the FDA Commissioners and the Health and Human Services (HHS) Secretaries of the Bush and Clinton Administrations saying importing drugs is unsafe, Canadian government officials themselves and many healthcare professionals on both sides of the border are opposed to importation.
- Most drugs sold outside the U.S. are not manufactured by a firm that has received FDA approval for that drug. Frequently, the drug is misbranded. And drugs purchased from a foreign source could be outright counterfeits.
- Even though a prescription drug may claim to come from Canada, it doesn't mean "Canadian medicine" is in the bottle. There is evidence of, what is purported to be, Canadian medicine coming from third-world countries, simply passing through Canadian borders and avoiding Canada's drug safety inspections and regulations. These so-called "prescription drugs" are entering Canada from Pakistan, South Africa, Thailand, Singapore, China and Iran.
- And those so-called "drugs" are not going to Canadian consumers. They're simply passing through Canadian post offices en route to the U.S. and other destinations. Canadian health officials have said they cannot be responsible for the safety and quality of prescription drugs entering the U.S.
- Scam artists prey on seniors, the suffering and even children by selling fake medicines through Canada, foreign Internet pharmacies and discount drug fronts. As the Washington, D.C. anthrax attacks proved, it's impossible to trace the origins of mailed substances.
- Comparisons between U.S. and Canadian prescription drug prices are misleading. Currency exchanges alone account for a large difference. In addition, many people pay substantially discounted prices through their health plans. Patients without prescription drug coverage can save by shopping around or by tapping into patient assistance programs through, among other places, www.helpingpatients.org as well as Medicare prescription drug discount cards.

LEGAL IMPLICATIONS

- Importing drugs is illegal. It's against U.S. law.
- Earlier this year, Maryland Attorney General office, at the request of the Maryland House of Delegates majority leadership, offered a legal opinion about the importation of drugs from Canada (Letter to The Honorable Kumar Barve from Office of the Maryland Attorney General, January 28, 2004). In that opinion, he stated that, "States (or local jurisdictions) that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, through a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability." He went on to say that, "while tort liability is a matter of some concerns, federal criminal prohibition, in my view presents a much more significant hurdle for such a program."

LIABILITY

- Under current conditions, American citizens must waive their right to the protection of American product liability laws when purchasing imported drugs from Canada.
- Importation could expand liability concerns for health care providers—Importation is a trial lawyer's dream. Pharmacists and hospitals could be liable even if they unknowingly dispensed or administered a counterfeit drug.
- A major contributor to higher prescription drug prices is excessive medical liability claims in the U.S. legal system. Statistics show this increased liability risk may account for nearly half of the differences in health costs between the U.S. and Canada and other developed countries (Ward Health Strategies, June 16, 2004).

The authors would like to acknowledge Shelby Payne, Dawn Sobieraj, and Elizabeth Stier, University of Maryland Pharm.D. Candidates for their assistance with this article.

toxtidbits 1-800-222-1222
the maryland poison center's monthly update. news. advances. information.
August/September 2004

Sorbitol Administered with Activated Charcoal... Is it Necessary?

Activated charcoal is often administered to poisoned patients to decrease the absorption of the drug/toxin. Many hospitals and Emergency Medical Services use activated charcoal products that also contain sorbitol. Sorbitol is a cathartic, as are magnesium sulfate and sodium sulfate. Cathartics have been advocated to decrease the absorption of poisons by accelerating the transit of the poison through the gastrointestinal tract. In addition, sorbitol is sweet and improves the palatability of activated charcoal. But, are cathartics such as sorbitol safe, effective and necessary?

There is no evidence to suggest that the combination of activated charcoal and a cathartic is more effective in limiting the absorption or toxicity of a poison/drug than activated charcoal alone. Some advocate the use of sorbitol to reduce the risk of constipation; however, constipation is not a complication of a single dose of activated charcoal. Multiple doses of activated charcoal are sometimes recommended to enhance drug elimination. In these circumstances, constipation can occur. If at least four doses of activated charcoal are administered, a cathartic such as sorbitol should be given but only once. Cathartic use is not without risks. Adverse effects from repeated use or use in small children include dehydration, electrolyte abnormalities, hypotension, and elevated serum osmolality. Deaths have been reported due to severe fluid and electrolyte abnormalities after several doses of activated charcoal/sorbitol mixtures.

In short, sorbitol and other cathartics are not necessary and can be potentially harmful if given in repeat doses. Administration of activated charcoal without a cathartic is recommended in adult and pediatric patients. If a cathartic is used with multiple dose activated charcoal regimens, it should be limited to a single dose to minimize the risk of adverse effects.

Lisa Booze, PharmD, CSPI

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Some antidotes such as Crofab® and Antizol® are not often used and are not always stocked in adequate quantities. The Maryland Poison Center keeps track of which hospitals have these antidotes and assists in locating and obtaining antidotes from nearby hospitals if needed. One more reason to call the Maryland Poison Center about all of your poisonings!

Maryland Poison Center
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Continuing Education for Pharmacists

Volume XXI, No. 5

Patient Counseling: Smallpox: Part 2: The Vaccine

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this two-part lesson series is to present information about smallpox and the smallpox vaccine as well as other means of prevention, and to answer questions about the disease and safety issues concerning vaccination.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge about the composition of the smallpox vaccine;
2. identify specific points pertaining to safety of the smallpox vaccine, and state the expected symptoms following vaccination;
3. recognize major features associated with adverse reactions to the smallpox vaccine and state how these are controlled; and

This lesson is provided by an educational grant from

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4. identify specific information of concern to patients, and state appropriate professional responses to them.

Smallpox Eradication

Prior to 1972, smallpox vaccination was recommended for all children in the U.S. at age one year. Most states required that children be vaccinated before entering school. The last case of smallpox in the U.S. was reported in 1949. The number of cases worldwide dropped to 10 to 15 million in 1966 when an intensified global smallpox eradication program was initiated. By the end of 1975, smallpox had been eradicated around the world except for the Horn of Africa.

In 1980, the World Health Organization (WHO) certified that smallpox had been eradicated from the world, and recommended that all countries cease vaccination and that all remaining stocks of variola (i.e., smallpox) virus be destroyed or transferred to one of two WHO reference laboratories – the Institute of Viral Preparations in Moscow, or the Centers for Disease Control and Prevention (CDC) in Atlanta.

Vaccine Characteristics

Smallpox vaccine that is currently available (Dryvax/Wyeth) contains vaccinia virus and cannot spread smallpox. This vaccine was prepared originally from calf lymph using a seed virus obtained from a strain of vaccinia virus. It is a lyophilized (freeze-dried) powder in 100-dose vials to be reconstituted with 50 percent glycerin. The vaccine is administered by a multiple puncture technique using a bifurcated needle. Detailed information concerning reconstitution and administration of smallpox vaccine is available on the CDC smallpox website at www.cdc.gov/smallpox.

Efficacy

Vaccinia vaccine produces neutralizing antibodies that are genus-specific and protective for other *Orthopoxvirus* sp. (e.g., cowpox, monkeypox, smallpox) viruses. Antibodies can be detected 10 days after primary vaccination, and seven days after revaccination. Neutralizing antibody titers persist in 75 percent of persons for up to 10 years after receiving second doses, and up to 30 years after receiving three doses of vaccine.

Epidemiologic data have shown that vaccination before exposure afforded protection against smallpox approaching 100 percent, and that it persisted for up to five years after primary vaccination. Protection was substantial, but less, for 10 years or more. Revaccination induced a greater period of immunity than that which occurred after primary vaccination alone.

Vaccination also provided substantial protection if administered within three days after an exposure to smallpox. Secondary cases were reduced up to 91 percent compared with unvaccinated people. Vaccination four to seven days after exposure to smallpox offered some

Table 1
Approximate Timing for Vaccination Reactions

Day	Description
0	Vaccination
3-4	Papule
5-6	Vesicle with surrounding erythema
8-9	Well-formed pustule
8-12	Maximum erythema
12+	Pustule crusts over with scab formation
17-21	Scab detaches revealing scar

Source: Centers for Disease Control and Prevention

protection from the disease or modified the intensity of symptoms. As when given before exposure, post-exposure vaccination provided protection for up to five years.

Vaccination Reaction

Professional labeling that accompanies the smallpox vaccine describes the reaction to be expected. Vaccinia virus replicates in the epidermal basal cell layer. Vaccination results in development of a lesion at the site of inoculation. A papule (small, solid elevation) appears at the inoculation site within three to four days following primary vaccination. Approximately five to six days following vaccination, a vesicle (blister containing clear fluid) surrounded by erythema (redness) forms at the site. The vesicle appears pustular by eight to nine days after vaccination. Maximum erythema occurs eight to 12 days after vaccination. The color then fades, the pustule dries, and a crust develops two to three weeks post-vaccination. By day 17 to 21, the crust (scab) separates and a permanent scar is noted at the vaccination site. This response to vaccination (Table 1) is termed a *major reaction*, and its appearance substantiates that vaccination was successful. A revaccinated person may develop a skin response similar to the major reaction that followed primary vaccination, but onset of the lesion occurs more rapidly than after primary vaccination.

Not all individuals will develop the typical skin response following vaccination. Non-typical reactions are referred to as *equivocal*. Several factors may cause them: (1) the person may be sufficiently immune to viral replication; (2) the person may be allergic to a component of the vaccine and develop a hypersensitivity reaction at the site; or (3) the vaccine may be subpotent or have been administered incorrectly. Any equivocal response to vaccination is an indication that the person should be revaccinated.

Live vaccinia virus will be present at the vaccination site beginning three to four days after vaccination through the period when the scab separates from the skin. The developing lesion may itch, so special care must be observed to avoid scratching and then touching other parts of the body or other persons which could transfer the virus to these sites (i.e., auto-inoculation) or other individuals. Health practitioners who have received the vaccine are directed to change the bandaging each day and to wash their hands immediately and thoroughly after touching the vaccination site or dressing.

Vaccination Schedule and Use

In the U.S., routine smallpox vaccination of children was discontinued in 1972, of health care workers in 1976, and in military recruits in 1990. Vaccination was recommended in 1980 for laboratory workers and health care workers who were at risk for occupational exposure to vaccinia or other *Orthopoxvirus* sp. that infect humans. This was intended for persons involved in handling cultures or animals contaminated or infected with non-highly attenuated vaccinia viruses, and recombinant vaccinia viruses derived from non-highly attenuated vaccinia strains.

The CDC published guidelines in 2001 for use of smallpox vaccine in the event of an *intentional* release of smallpox virus. If there should be such release of variola virus, vaccination would be given to those exposed to the initial release, all contacts of people with smallpox, and to all others at risk of exposure. Those at risk include (1) persons involved in the direct medical care or transportation of confirmed or suspected smallpox patients; (2) laboratory personnel involved in collecting or processing clinical specimens from confirmed or suspected smallpox patients; (3) workers who may come into contact with infectious materials including medical waste, bed linens, etc.; (4) those involved in room disinfection in facilities where smallpox patients are present; and (5) any other persons or groups as recommended by public health authorities. These would include medical, law enforcement, emergency response, or military personnel.

The dose for smallpox vaccine is one successful inoculation (i.e., a dose that results in a major reaction at the vaccination site). The current vaccine should not ordinarily be administered to persons less than 18 years of age, but in an emergency situation there probably will be no age limitation for vaccination.

Adverse Reactions to Vaccine

Current concern with smallpox vaccine is not so much with its efficacy which has been substantiated, but rather with its safety. A compilation of surveys published in 1968 revealed that approximately 1250 persons in every million who received the vaccine developed reactions that were serious, but not life-threatening. Serious reactions were more rare after revaccination, occurring at a rate of 108 per one million vaccinations. CDC believes that adverse event rates in the U.S. today may be higher since there are more people at risk from immunosuppression (e.g., from cancer and its therapy, organ transplants, and

illnesses such as HIV/AIDS). To counter this, outcomes associated with adverse events may be less severe because of advances in medical care.

Mild to Moderate Reactions. ***Pain*** of mild intensity at the site of inoculation was reported by 40 to 47 percent of vaccinated persons with 2 to 3 percent reporting the pain as severe. Axillary lymphadenopathy (swollen, painful lymph nodes) was noted in about one-third of recipients; most lymphadenopathy was mild, but 3 to 7 percent of subjects considered it to be moderate in intensity (i.e., bothersome but not sufficient to interfere with normal activities).

Fever was common seven to 12 days after vaccination. In one study, vaccine was given to unvaccinated adults. Five to 9 percent of recipients developed a fever of ≥100° F, and 3 percent reported temperature of ≥102° F.

In addition to fever, adults also reported ***constitutional symptoms*** such as chills, fatigue, headache, myalgias, and nausea on or about the eighth or ninth day after vaccination; 1 to 2 percent of recipients reported these symptoms as severe. Historically, fever was more common among children, with about 70 percent of them experiencing one or more days of temperature ≥100° F after primary vaccination. Fifteen to 20 percent of children experienced temperatures of ≥102° F.

Since live vaccinia virus will be present at the site of vaccination beginning three to four days after vaccination, from that point through day 14 after vaccination it can be anticipated that there will be maximum viral shedding. Vaccinia was recovered from the site until the scab separated from the skin.

The most frequent complication of smallpox vaccination was ***inadvertent inoculation*** (transfer of virus to close contacts, or autoinoculation). This accounted for close to one-half of all complications of vaccination and revaccination. Studies estimated the rate of inadvertent inoculation to be 529 cases per one million primary vaccinations, with the face, eyelid, nose, mouth, genitalia, and rectum being the most common sites. Lesions of the eye resulted in scarring of the cornea in some persons, with serious impairment of vision. Most other lesions healed without specific treatment.

Generalized vaccinia is a rash believed to result from vaccinia viremia with implantations in the skin in persons who do not have preexisting skin disease such as eczema. Vesicles or pustules can appear on normal skin distant from the vaccination site. Most generalized vaccinia rashes in the past were self-limited and required minor or no therapy. Patients with serious underlying immunosuppressive illnesses or whose conditions might be otherwise toxic may require treatment. In the 1968 report cited above, generalized vaccinia rash occurred at a rate of 242 cases per million primary vaccinations.

Erythematous or ***urticarial rashes*** appeared approximately 10 days after primary vaccination. The individual was usually afebrile, and the rash diminished spontaneously within 24 days. On rare occasions, bullous erythema multiforme (Stevens Johnson syndrome) occurred.

Moderate to Severe Complications. ***Eczema vaccinatum*** is described as a localized or systemic dissemination of vaccinia virus in persons who have eczema or atopic dermatitis, or a history of these inflictions. It was also seen in contacts of vaccinated persons who had eczema or atopic dermatitis, or a history of these skin disorders. Though usually mild and self-limited, eczema vaccinatum was of moderate to severe intensity or even fatal in some cases, being most severe in persons receiving primary vaccination. In the 1968 study report, eczema vaccinatum was estimated to occur in 39 persons per million primary vaccinations.

Progressive vaccinia (*vaccinia necrosum*; v. *gangrenosa*) is a severe illness noted by progressive necrosis in the area of vaccination that can spread to adjacent skin, bones, and to viscera. Metastatic lesions were common. Progressive vaccinia occurred almost exclusively in persons with cellular immunodeficiency. In the 1968 reports, it appeared in approximately one to two persons per one million primary vaccinations. Progressive vaccinia was almost always fatal before the introduction of vaccinia immune globulin and the antiviral agents discussed below.

Post-vaccinial encephalitis affects persons <2 years of age receiving primary vaccination, or adolescents and adults receiving primary vaccination. Symptoms included a variety of CNS signs such as ataxia, confusion, paralysis, seizures, or coma. Most responses were believed to result from autoimmune or allergic reactions rather than direct contact between the virus and the nervous system. It has been reported in three to 12 persons per one million primary vaccinations. Approximately 15 to 25 percent of affected persons died and another 25 percent developed permanent neurological sequelae including paralysis. There is no specific therapy for post-vaccinial encephalitis.

Fetal vaccinia is a rare complication of smallpox vaccination with fewer than 50 cases having been reported. Fetal vaccinia usually occurred after primary vaccination of the mother during early pregnancy, and resulted in stillbirth or death of the infant soon after delivery. Smallpox vaccine is not believed to have caused teratogenic malformations.

Death following smallpox vaccination was rare. From past experience, one or two people in 1,000,000 primary vaccinations, and one per four million persons who were revaccinated died. Death most frequently followed post-vaccinial encephalitis or progressive vaccinia. These figures may change since recently there have been at least

Table 2
Contraindications for Routine Non-emergency Vaccine Use

- Infants <2 years of age; vaccination should not ordinarily be given for non-emergency use in children <18 years of age
- Persons with eczema or other acute, chronic, or exfoliative skin conditions or those with past history of these disorders
- Persons of any age receiving systemic corticosteroids (equivalent to ≥20 mg/day of prednisone for ≥2 weeks), immunosuppressive drugs, or radiation therapy
- Persons with immunosuppression (e.g., cancer, solid organ transplantation)
- Individuals with congenital or acquired deficiencies of the immune system
- Women who are pregnant or suspected to be pregnant
- Persons allergic to any component of the vaccine

Source: www.fda.gov/cber/label/smalwye102502LB.htm

two deaths of vaccine recipients in whom it was not contraindicated.

Vaccination Contraindications
Smallpox vaccine is contraindicated for individuals who have any of the conditions listed in Table 2, or live with someone who does. In the event of exposure to smallpox virus, there would be no contraindications because the benefit of vaccination would greatly outweigh its risk for complications.

Vaccinia Immune Globulin
Vaccinia Immune Globulin (VIG) is currently the primary treatment for complications of smallpox vaccination. It is available to state health departments through CDC.

A sterile solution of the immunoglobulin fraction of plasma from persons vaccinated with smallpox vaccine, VIG is effective in the treatment of eczema vaccinatum, serious generalized vaccinia, and serious manifestations of inadvertent inoculation. It is also indicated for progressive vaccinia, although it has variable effectiveness in treating this complication. Since post-vaccinial encephalitis was not due to virus multiplication, VIG would not be effective in treating it.

VIG should be used only for treatment of smallpox vaccine complications that have serious clinical manifestations. The immune globulin must be administered intramuscularly, and as soon as possible after onset of symptoms. A highly purified intravenous formulation of VIG (IV-VIG) is in development. Like VIG, it is available through CDC under an Investigational New Drug (IND) protocol.

Cidofovir (Vistide/Gilead) is an antiviral medication approved for use in treatment of CMV retinitis. Having shown some activity against vaccinia virus, it is unclear how well cidofovir would work in treating vaccinia infections in humans. Cidofovir, therefore, remains second-line treatment after VIG for complications of smallpox vaccination, although cidofovir is not yet approved.

Post-exposure Infection Control
Should smallpox be confirmed, all persons in whom the infection is suspected need to be isolated immediately. All household and other close contacts should be vaccinated and placed under surveillance. Because widespread dissemination of smallpox virus by aerosol imposes a serious threat in hospitals, patients should be isolated at home whenever possible. This approach seems reasonable for most patients, given there is little that can be done other than supportive therapy.

Discretion should be used when identifying contacts to ensure that vaccination and appropriate surveillance measures will be directed to those at greatest risk. Contacts are defined as persons from within the same household or others who have had face-to-face contact with the infected patient after onset of fever. (Patients do not transmit infection until after fever has given way to the onset of rash.)

All contacts of exposed patients should ideally be isolated, even though if they are infected, they are not contagious until onset of rash. One strategy directs that contacts have temperatures checked at least once daily, preferably in the evening. An increase in temperature to ≥101° F during the 17-day period following the last exposure suggests the possible development of smallpox and would indicate isolation until it can be determined whether the contacts have smallpox. All close contacts of an infected patient should be vaccinated promptly.

Overview
There is no proven treatment for smallpox, but it can be prevented through use of the smallpox vaccine. Prevention by vaccination prior to exposure approaches nearly 100 percent efficacy. The vaccine carries a degree of serious adverse effects, most of which are not life-threatening; however, it has a mortality rate of one or two deaths per each 1,000,000 vaccinations. At the time of publication of this article, some problems were beginning to appear in health care and military personnel who had recently received the vaccine. Previously generated morbidity and mortality statistics with smallpox vaccine may, therefore, be changing. For further updates, check CDC's website: www.cdc.gov/smallpox.

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Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Smallpox: Part 2, The Vaccine". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 4/15/06. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-03-005-H01.

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1. All of the following are members of the *Orthopoxvirus* species EXCEPT:
   a. cowpox.
   b. monkeypox.
   c. chickenpox.
   d. smallpox.

2. Vaccinia virus replicates in the:
   a. hepatic endothelial reticulum.
   b. epidermal basal cell layer.
   c. lymphatic B cells.
   d. subdermal nerve cells.

3. Which of the following reactions is most likely to occur eight to 12 days after administration of smallpox vaccine?
   a. Maximum erythema
   b. Formation of small papule
   c. Vesicle with clear fluid
   d. Scab detachment

4. Routine smallpox vaccination in military recruits in the U.S. ended in:
   a. 1972.
   b. 1976.
   c. 1980.
   d. 1990.

5. The adverse reaction to smallpox vaccination characterized by swollen, painful lymph nodes refers to:
   a. axillary lymphadenopathy.
   b. generalized vaccinia.
   c. eczema vaccinatum.
   d. vaccinia necrosum.

6. The most frequent complication of smallpox vaccination was:
   a. erythematous rashes.
   b. generalized vaccinia.
   c. inadvertent inoculation.
   d. vaccinia necrosum.

7. The adverse reaction to smallpox vaccination characterized by necrosis in the area of vaccination is referred to as:
   a. eczema vaccinatum.
   b. generalized vaccinia.
   c. inadvertent inoculation.
   d. progressive vaccinia.

8. Vaccinia immune globulin is effective in treating all of the following EXCEPT:
   a. inadvertent inoculation.
   b. post-vaccinial encephalitis.
   c. generalized vaccinia.
   d. eczema vaccinatum.

9. Prevention of smallpox by vaccination prior to exposure approximated nearly:
   a. 10 percent.
   b. 33 percent.
   c. 50 percent.
   d. 100 percent.

10. Patients with smallpox do not transmit infection until after:
   a. the fever has given way to onset of rash.
   b. the rash has given way to onset of fever.

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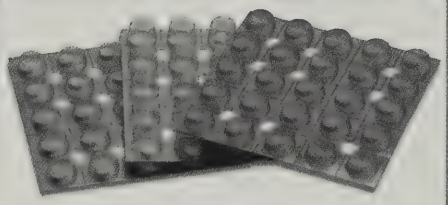

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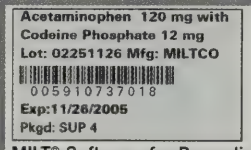

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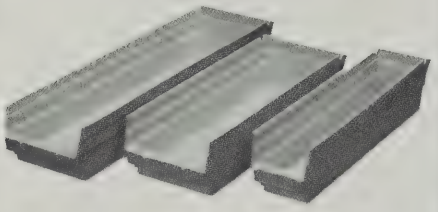

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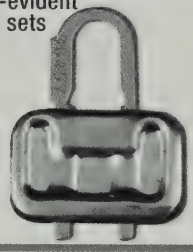

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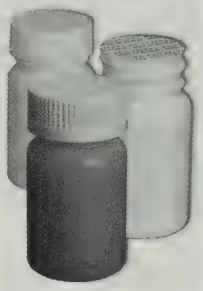

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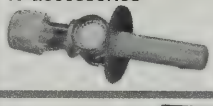

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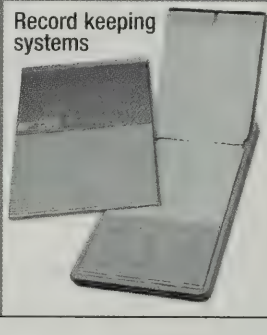

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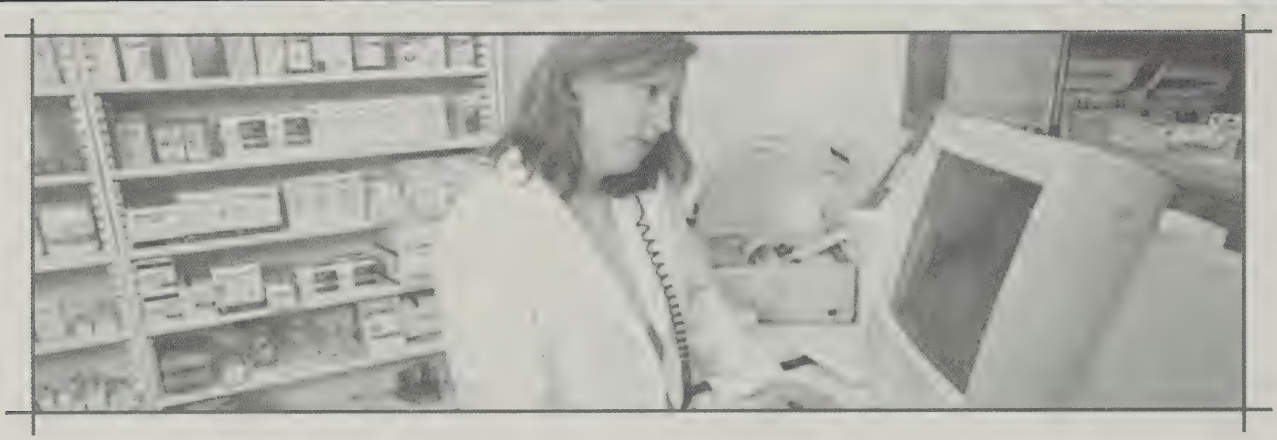

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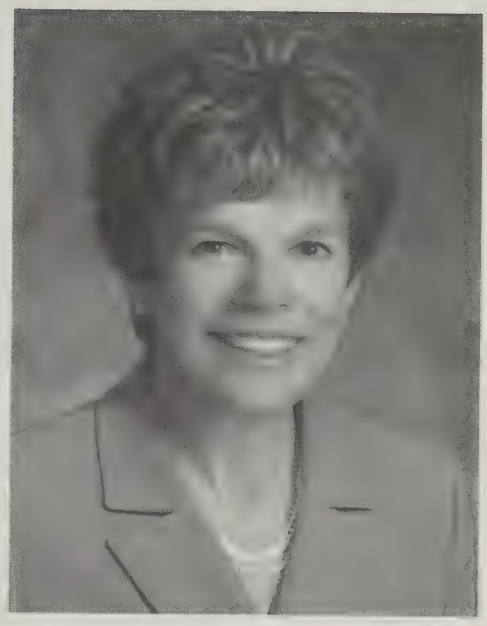

Cynthia Boyle, Pharm.D.
President

For those of you who have been involved with a home improvement project, you will understand how such renovation relates to current MPhA initiatives and plans. If you think of the Association metaphorically as our "home," we are satisfied with many of the features, according to the strategic planning responses a year ago. However, we would like updated components to improve functionality, satisfaction, and value. We want to keep the key attributes and character, while helping our Association home to become more responsive and inclusive.

At this midpoint in the MPhA activity year, the Board of Trustees has responsibly maintained our Association. Just like homeowners, we have paid salaries and bills, renewed insurance, audited records, and contracted for housekeeping. We have updated Executive Director Howard Schiff's professional services contract and will benefit from his continued dedication to MPhA. We have approved a balanced budget which does not draw from reserves. We have approved Kathryn Fader as a new member to capably serve with MPhA members James Bresette and Michael Souranis on the Continuing Education Coordinating Council which accredits programs for pharmacy organizations.

For renovations this year, I invited each trustee to volunteer for a Goal Group based upon the Association goals approved at the House of Delegates in June, 2004. Each group was asked to develop short-term and long-term objectives for their goal, determine leadership, recruit at least two MPhA members not currently on the Board of Trustees to participate, and create a timeline with action items. To assist each group, we are devoting each trustee meeting to a goal by extending discussion time for ideas and suggestions. I especially appreciate the trustees' willingness to experiment with this format which has been meaningful and productive.

Goal Group #1:
To develop and implement professional programs to enhance pharmacists' **professional competence**. This group is being assisted by Convention Chairperson Ginger Apyar and *Maryland Pharmacist* Pharmacy Editor Catherine Cooke. The members are developing sample protocols for pharmacists to implement collaborative practice, developing and promoting quality continuing education programs, and working with the School of Pharmacy to promote immunization training for pharmacists.

Goal Group #2:
To develop and implement **effective communication** to promote professional services and education. Under the leadership of Kellie Monzillo, this group has looked at what is working, what is not working, and what is missing for the various ways MPhA communicates with the membership and external entities. The group seeks to improve the website and our publications, and to unify and promote consistency in all MPhA communications through one logo and a motto consistent with our mission. MPhA is fortunate that Mel Rubin, Maryland State Board of Pharmacy President, significantly serves as contributing author to our valuable newsletter.

Goal Group #3:
To develop and implement **effective legislative agendas and strategies**. Steve Wienner is leading this group which seeks to increase MPhA member participation in Legislative Day the morning of February 17 in Annapolis, to sharpen MPhA's legislative focus, and to promote MPhA as a resource for pharmacy information for legislators before and after the General Assembly session. This goal synergizes with the following goal for collaborative efforts.

Goal Group #4:
To develop and implement programs that maximize **collaborative efforts**. It is my pleasure this year to serve as chairperson of the Maryland Pharmacy Coalition (MPC) which is MPhA's primary means of professional collaboration in Maryland. Future MPC meetings are April 14 and July 14; they will focus on creation of a leadership development seminar and early planning for American Pharmacists

Month in October 2005. Also, MPhA collaborated with APhA-Academy of Student Pharmacists to exhibit at the regional meeting in Philadelphia in October. Bill Ellis of the APhA Foundation has volunteered to help our foundation with future organizational planning and direction. Notably, the self-directed Eastern Shore Pharmaceutical Society is an example of sustained collaborative success. Through regular continuing education programs and partnership with the Eastern Shore Area Health Education Center, pharmacists from community, institutional, and clinic practice settings discuss pharmacy concerns to meet their area needs. I find their camaraderie engaging and reminiscent of the area associations previously coordinated within MPhA.

Goal Group #5:
To **enhance membership services** leading to increased membership. Vice Speaker Mary Kremzner and her group are working to increase recent graduate membership by 10% each year beginning in 2005, to broaden MPhA's membership base, to incentivize members, and to expand MPhA promotional and marketing efforts by working closely with the Effective Communication Group.

Goal Group #6:
To develop and implement **processes to strengthen the Association**. This group is literally the foundation of MPhA. Treasurer Phil Cogan drafted the balanced budget; Constitution and By-Laws Chair Mark Sanford and his committee will be submitting a proposal to members to streamline and improve the Association's governmental processes; Maryland Pharmaceutical Foundation Chair Paul Holly and his board of directors are actively implementing strategies for fundraising to support practice initiatives and to sustain the B. Olive Cole Museum. First Vice President Matt Shimoda completed an important duty to secure nominations for MPhA's future leadership. Non-dues revenue remains elusive, but vital.

Important decisions and events will occur in 2005 before the June convention, starting with Legislative Day. First-time participants will have support. Please consider nominating worthy individuals for one of our premier awards, including the new MPhA Mentor Award. House of Delegates Speaker and Vice Speaker John VanWie and Mary Kremzner will be asking members for policy resolutions to be enacted by the House in June.

In my presidential address theme "*Light the Fire - Pass the Torch*," I had been tempted to add, "but do not burn the house down." We did not have to burn the house down for our renovations. In the months ahead, I want to concentrate on passing the torch to student pharmacists and new practitioners who will live in this house some day.

I know you join me in extending appreciation to all MPhA staff and volunteers who support the Association with conviction, creativity, determination and respect for our profession. Looking ahead, I hope you will participate in all or part of the MPhA convention in Ocean City, June 11-14. If you haven't already, make it your tradition.

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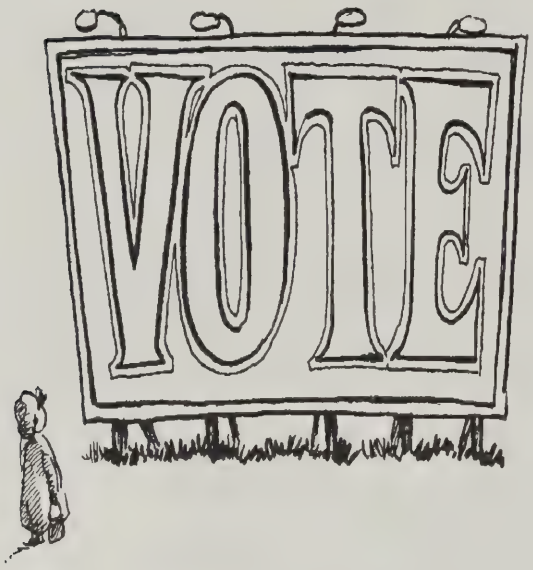

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Duquesne University, 1973
Practice Site – Giant Pharmacy

Allow me to share with you, that I was "very touched, yet humbled" to be recognized as a "Distinguished Honorary Alumnus" at the University of Maryland School of Pharmacy Graduation Banquet, May 2004, sponsored by its outstanding alumni association.

Pharmacists today, in many spheres of practice, find themselves inundated with many issues, while striving to adhere to the "safety and reliability" code that they deem essential to their patients and fellow healthcare colleagues. Corporate American might choose to call this "multi-tasking," yet when this might involve superfluous issues, are we being asked to compromise the innate goals that were highly instrumental in our choosing of pharmacy as our professional careers. Has "bottom line" economics invaded our spheres of practice? Certainly! To a large degree, if we are honest with ourselves.

Your Maryland Pharmacists Association offers its members and actually, all pharmacist colleagues, a highly committed group of practitioners and professionals that encompass many spheres and disciplines, from community, to hospital, to long-term care, to independent owner, consultants, educators and faculty administrators that strive to promulgate pharmacy's mission of practicing the "best patient care" in all areas, without compromise to safety.

I offer to you, our MPhA membership, an "open ear" to your concerns and an avenue for your issues. Having served presently and prior, as an elected trustee, vice president, and speaker of the house, I have, and will continue a near perfect meeting attendance and voice for our mutual concerns, and the vitality of our practice setting and patient care. I sincerely request your consideration of my candidacy for your MPhA Second Vice President. Thank you.

Treasurer

Walter Abel, R.Ph.

I, Walter Abel, with respect and appreciation, accept the Board's nomination for the office of the Treasurer of the Maryland Pharmacists Association.

Pharmacy has been my profession, my passion, and my livelihood for all of my adult life. It is in the interest of promoting the profession that made me come to the Board meetings and participate as an interested member for the last year and a half. Given the opportunity to become an officer on the Board will give me that much more leverage to make a difference in our profession. If I am elected Treasurer, I promise to conscientiously and prudently watch over the organization's finances and do whatever else would be permitted by my office to make a difference in the well being of my fellow pharmacists. I thank you for the nomination. Sincerely, Walter H. Abel

Trustee Seat # 1

Michelle Andol, R.Ph., J.D.

B.S., UMB, School of Pharmacy 1990
J.D., UMB, School of Law 1996
Current Employment: Harlem Gardens Pharmacy, Independent Retail Practice

Ms. Andoll is a graduate of the University of Maryland School of Pharmacy and the University of Maryland School of Law. For over 14 years, she has worked in a variety of pharmacy settings, including hospital, infusion therapy, retail and long-term care. These experiences include management and supervisory positions as well as staff and clinical roles.

Before opening Harlem Gardens Pharmacy, Ms. Andoll held the position of Pharmacist Compliance Officer for the Maryland Board of Pharmacy for several years. As the Compliance Officer, she oversaw the compliance and disciplinary functions for the Board. These experiences will surely help Ms. Andoll to serve you well as a Trustee for the MPhA.

Scott S. Kuperman, P.D.

Phone: 410-997-1606 (W)
Email: scott.kuperman@neighborcare.com
MPhA member since 1988
Maryland Practice Experience: Independent Community Pharmacy, Chain Community Pharmacy, Pharmacy Education

I have worked over 15 years in community practice, the first ten of which were as a pharmacy manager for an independent. Here I became well acquainted with the difficulties and rewards inherent in this setting. I have seen our profession constantly assailed on all sides by third party issues as we attempt to provide vital clinical services to our patients. From this experience it has become clear to me that pharmacists must be pro-active in dealing with such situations. I believe that becoming active in MPhA is one of the best ways to accomplish this goal.

I have been a preceptor for UMB for over a decade. I became a preceptor because of my belief in "giving back". I try to teach my students the importance of being the best practitioners they can be and how their efforts can benefit the profession and society as a whole.

For the past 5 years I have been a compounding pharmacist for NeighborCare Pharmacies, acting as the company's compounding information resource as well. From this dual role, I have learned how approaching situations creatively results in finding novel solutions to difficult problems, as well as the importance of networking and teamwork for the benefit of the greater good.

This past year I have been serving as an interim trustee for MPhA, where I have witnessed first-hand the workings of our organization and the state of practice in Maryland. I have had the privilege of working with an exceptionally dedicated board, with whom I hope to be able to continue.

With your help, I would like to continue devoting my energy and experience to supporting those programs which will benefit all of us and our profession. Thank you for your consideration.

Trustee Seat #2

Barry Poole, R.Ph.

My practicing pharmacy experience has been with independent community pharmacies. I have been extremely fortunate to be able to work for three such pharmacies in my professional career. In 1971, my first position was with Hillcrest Heights Drugs for whom I worked full time until my FDA career began and then part-time until the store closed. My next community practice site was Wilde Lake Pharmacy in Columbia. Currently I work part-time at Watermont Pharmacy, a family owned pharmacy since 1961. These experiences have taught me that the pharmacist is the caregiver and caretaker of the community.

At this time, I serve as the Director of the Division of Drug Information, Office of Training and Communication, Center for Drug Evaluation and Research. In this capacity, I supervisor a staff of 20 that consists mainly of Pharm.D.s. The Division is charged with the responsibility of responding to inquiries from a broad range of sources, including regulated industry, academia, health care professionals, consumers and others. I joined the agency in 1974 and have served in various capacities as a Pharmacist, Technical Information Specialist, Consumer Safety Office and Senior Consumer Safety Officer in various offices within the Center.

I view the MPhA as the caregiver and caretaker of the Maryland pharmacist community. As I have been privileged to work various fields of pharmacy, I would consider serving as a Trustee in the MPhA an even greater privilege. The MPhA must remain an active and vital part of the Maryland pharmacist community and this can be done by reaching out to all who practice the profession. Promotion of the MPhA, what it does and what it can do for all pharmacists in Maryland, is of paramount importance to the future well being of the our profession. My goal would be to get this message out, to increase the membership base, and revitalize this bastion of support for Maryland pharmacists .

I am a graduate of the University of Maryland, School of Pharmacy in 1971 with a Bachelor of Science Degree in Pharmacy.

David Russo, P.D. MBA, J.D.

25 N. Cannon Avenue, Hagerstown, MD 21740
University of Maryland, School of Pharmacy, 1979
Community Independent Practice, Russo's Rx

I appreciate the consideration of the nominating committee. It would be an honor and a privilege to serve the MPhA on the Board of Trustees.

Time sure flies! My professional career, though primarily community independent, includes experience in hospital, infusion services, and poison control. Throughout my career, I have been active, at various times, with the school of pharmacy, and the MPhA. I have held leadership positions in an owner's advisory council, my local pharmacists association, and the Maryland State Board of Pharmacy.

I believe that involvement is the best method to understand, mediate, and effect the growth and development of our profession. The issues, threats, and opportunities keep coming at our profession. It's apparent that we need to continue in our proactive attempt to chart

our own course, or others will do it for us. It's a continual process that requires vision, collaboration, negotiation, and consensus building.

As a trustee, I intend to maximally utilize my diverse professional and managerial experience, leadership and communication skills, business and legal education, and vision, to serve the MPhA in enhancing the growth and development of the profession of pharmacy. Thank you for your support.

Trustee Seat # 3

Dennis Eaton, R.Ph.

Mt. Carmel Pharmacy 1986-Present
B.S. Pharmacy U of Maryland 1980
B.S. Zoology U of Maryland 1974

I am interested in expanding my knowledge, and involvement in the Maryland legislative process. I will support issues that represent all facets of pharmacy, retail, hospital, and academia.

I am interested in pursuing better freedom of choice legislation that allows patients to fill prescriptions where they prefer without the financial penalties now being seen with mail order.

Doris Voigt, Pharm.D.

A 1969 graduate of Albany College of Pharmacy, with experience in community–independent and chain, after completing an institutional apprenticeship at Tompkins County Hospital in Ithaca, New York, Dr. Voigt relocated to Maryland in 1972. She began her Maryland based Pharmacy Practice in U.S. Government Service at Fort Meade. She currently holds the rank of Lieutenant Colonel in the U.S. Army Reserve.

After her "retirement" from Civil Service, she accepted a position at The Walter P. Carter Hospital in downtown Baltimore. There she developed a sensitivity for those afflicted with mental and substance abuse diseases. She is currently employed as Lead Pharmacist for Kaiser Permanente in Annapolis, Maryland; this provides the Managed Care experience.

She completed her Pharm. D. in 2004 through the Non-Traditional Pathway of University of Maryland, School of Pharmacy in the minimum three-year prerequisite.

An active member of American Pharmacists Association, American Society of Health System Pharmacists, Maryland Society of Health System Pharmacists, Washington Metropolitan Society of Health System Pharmacists as well as Maryland Pharmacists Association she knows all to well the role they provide in the dissemination of information. As a Member of Pharmacists' Assistance and Education Committee, she serves to assist fellow Pharmacists on their journey to recovery while maintaining the level of care rendered the public at large.

Dr. Voigt is active in the augmentation of the educational experience of the upcoming Pharmacy Practioners. She began Precepting Pharm. D. Candidates in 1984. She was honored by University of Maryland in 2002 "Preceptor of the Year" and Albany College of Pharmacy in 2003 "Alumnus of the Year for Contribution to the Profession of Pharmacy".

Dr. Voigt strongly believes all Practioners (Pharmacists/ Technicians/Students) directly influence the future of the Profession of Pharmacy. It is incumbent upon all to participate for the whole. It is for this reason; she feels her role as Trustee, Maryland Pharmacists Association, as a Pharmacy Practioner with multi-level experience, provides the under-standing and compassion coupled with the vision for the future to enhance Maryland Pharmacists Association 's service to not only Members but to the Profession.

2005 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

Second Vice President

☐ Joseph Marrocco, P.D.

Treasurer

☐ Walter Abel, R.Ph.

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

☐ Michelle Andol, P.D.
☐ Scott Kuperman, P.D.

Trustee Seat # 2

☐ Barry Poole, R.Ph.
☐ David Russo, R.Ph.

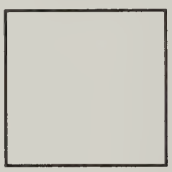
Trustee Seat # 3

☐ Dennis Eaton, R.Ph.
☐ Doris Voigt, Pharm.D.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, ***received by Friday, May, 6, 2005***. For questions, please call MPhA at 800-833-7587.

Only official ballots from the "Maryland Pharmacist" journal will be accepted—no photocopies.

Fold



2005 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

Recognizing Pharmacy Excellence
The 2005 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 123rd Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Friday, April 8, 2005.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1995 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. ***Who is Eligible:*** Any long standing contributor to the profession or the Association.

- **MPhA Mentor Award**
  This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the Award.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. ***Who is Eligible:*** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **Elan Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than ***Friday, April 8 , 2005***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ ***Pharmacist Mutual Distinguished Young Pharmacist Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Seidman Distinguished Achievement Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Elan Innovative Practice Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Wyeth-Ayerst Bowl of Hygeia***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***MPhA Mentor Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

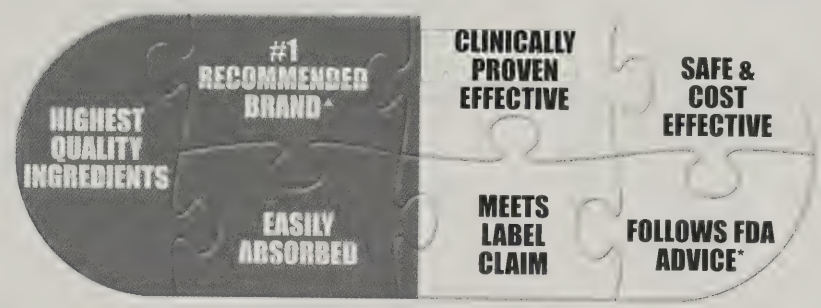
☐ ***MPhA Honorary President***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Recommend with Confidence



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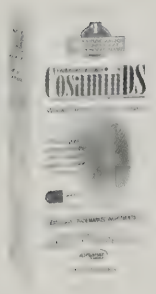

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▲ Source: Surveys conducted by *Orthopedic Today* of orthopedic surgeons and rheumatologists in April 2000, November 2001, and July 2003 relating to glucosamine/chondroitin sulfate brands

*The FDA has advice for consumers at http://vm.cfsan.fda.gov/~dms/ds-savvy.html on purchasing dietary supplements.

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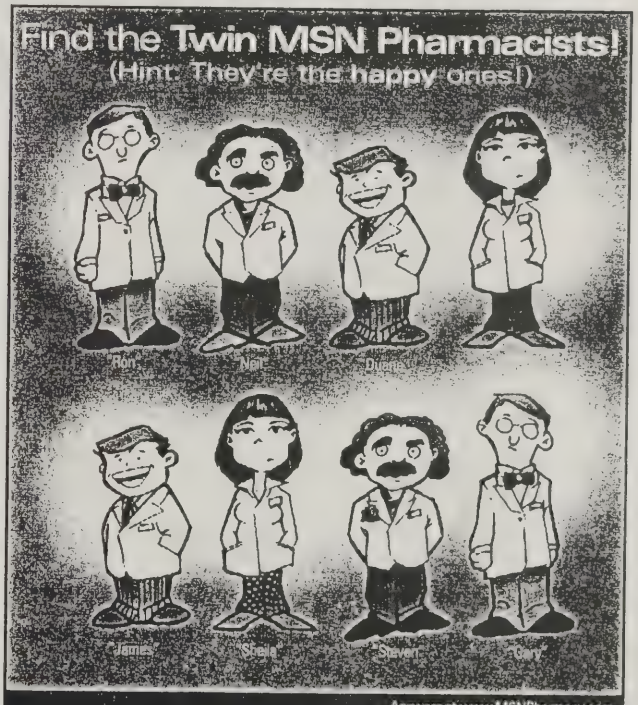

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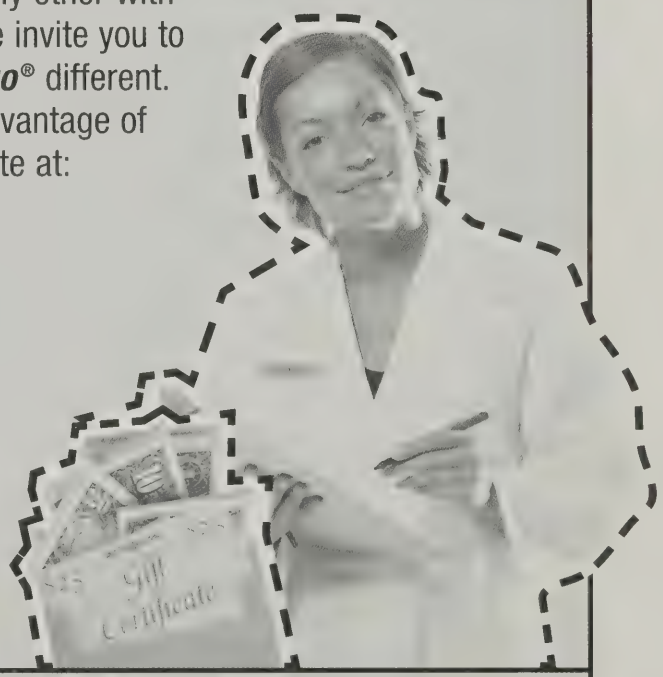

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This is the third of a four-part series on Drug Therapy Management. This series is intended to provide the community pharmacist with practical tips for improving care, generating revenue and increasing customer satisfaction.

"Drug Therapy Management Series: Part III: Focus on Emergency Contraception"

Authors: Deborah Sturpe, PharmD, BCPS[a] and Catherine E. Cooke, PharmD, BCPS[a,b]
[a]University of Maryland School of Pharmacy, [b]Pfizer, Inc.

In the United States, almost half of all pregnancies are unintended and occur in women of all ages and socioeconomic groups. The negative social, medical and economic consequences of an unwanted pregnancy are tremendous.[1] One of the available strategies to assist patients in preventing an unwanted pregnancy is the use of emergency contraception. Emergency contraception (EC) can be used when a contraceptive accident occurs (e.g., condom breaks), when birth control pills are missed, or when there is a lack of birth control use. Emergency contraception is defined as the use of a pregnancy prevention method after an act of unprotected intercourse has taken place. The most common forms of EC include hormonal methods or placement of a copper intrauterine device (IUD). This article will focus on the two hormonal regimens used, which include the Yuzpe regimen (estrogen plus progestin) and a progestin-only regimen. Providing access to EC in your pharmacy can increase customer satisfaction and generate increased revenue.

Emergency contraception has the same mechanisms of action as routinely used hormonal contraceptive methods (i.e., birth control pills) and primarily works through prevention of ovulation and/or inhibition of sperm migration and function.[2] Both these mechanisms of action ultimately prevent fertilization of ova by sperm. A tertiary mechanism of action may include prevention of implantation of a fertilized egg into the endometrium, but data thus far does not strongly support this as playing a role in the action of EC.[3] It is important to note that no form of EC interrupts with an already implanted, fertilized ovum. Consequently, EC is not an abortifacient.

The Yuzpe regimen consists of two doses of 100 mcg ethinyl estradiol plus 0.5 mg levonorgestrel or 1 mg norgestrel taken 12 hours apart. Administration of the Yuzpe method of EC can only be accomplished via use of various combined oral contraceptive pills (see Table 1) because production of the commercially available product, Preven®, was discontinued by the manufacturer in May 2004.

The progestin-only method of EC consists of administration of 1.5 mg levonorgestrel. Although originally approved for administration as two divided doses of levonorgestrel 0.75 mg given 12 hours apart, a World Health Organization trial demonstrated that a single dose of 1.5 mg was equally effective.[3] The progestin-only EC method is marketed as the commercial product Plan B®. Other products may also be utilized (see Table 1).

Emergency contraception should be utilized as soon as possible after unprotected intercourse to maximize effectiveness. Although the Yuzpe regimen may be administered up to 72 hours after unprotected intercourse and the progestin-only regimen up to 120 hours post-intercourse, both regimens are most effective when taken in the first 24 hours. Pregnancy rates, if taken within this shorter time frame, are 0.4% (progestin-only) and 0.5% (Yuzpe). The progestin-only regimen is slightly more effective than the Yuzpe regimen when taken beyond the first 24-hour period (pregnancy rates of 2.7% and 4.2%, respectively).[4] If the woman is already pregnant at the time EC is taken, the regimen will not cause harm to the fetus. A pregnancy test is therefore

unnecessary prior to administration. A woman presenting beyond 72 to 120 hours post-intercourse should be referred to her provider for consideration of IUD placement if appropriate.

Side effects of EC are generally mild. Nausea and vomiting are most common. Approximately 50% of women using the Yuzpe regimen experience nausea compared with only 23% of women using the progestin-only regimen. Consequently, pre-medication with an antiemetic such as over-the-counter meclizine is strongly suggested for the Yuzpe regimen. Doses should be repeated if the woman vomits within 30 minutes of administration.[4]

Pharmacists in Washington State have been providing EC to women for many years under a statewide collaborative practice protocol, and results have been positive. Notably, pharmacist provision of EC in Washington State has increased customer satisfaction.[6] Most women using the services reported they sought EC through a pharmacist due to convenience, and 42% of women stated they would not have sought EC elsewhere.[5] Although the State of Maryland does not have a blanketed collaborative practice agreement for EC, pharmacists are able to individually submit collaborative protocols for EC to the Board of Pharmacy (see Drug Therapy Management section at www.mdbop.org)

Because EC is a safe method for pregnancy prevention, determining if a woman is a candidate is fairly simple (see Table 2). If a woman is a candidate, Plan B® is now the preferred method for EC in most settings due to superior efficacy, lower side effects, and potential for single dose administration. In addition, there is also an EC hotline where women can be referred (877-994-6432).

Emergency contraception is a safe and effective method for prevention of unwanted pregnancy after unprotected intercourse or other contraception mishaps. Provision of EC through your pharmacy can increase customer satisfaction and generate revenue.

Table 1: EC dosing and products

Product Name	Estrogen per tablet	Progestin per tablet	Dose
Yuzpe regimen			
Alesse®	20 mcg EE	0.1 mg L	5 pink tablets, repeat 12 hours later
Aviane®	20 mcg EE	0.1 mg L	5 orange tablets, repeat 12 hours later
Cryselle®	30 mcg EE	0.3 mg N	4 white tablets, repeat 12 hours later
Enpresse®	30 mcg EE	0.125 mg L	4 orange tablets, repeat 12 hours later
Lessina®	20 mcg EE	0.1 mg L	5 pink tablets, repeat 12 hours later
Levlen®	30 mcg EE	0.15 mg L	4 light orange tablets, repeat 12 hours later
Levlite®	20 mcg EE	0.1 mg L	5 pink tablets, repeat 12 hours later
Levora®	30 mcg EE	0.15 mg L	4 white tablets, repeat 12 hours later
Lo/Ovral®	30 mcg EE	0.3 mg N	4 white tablets, repeat 12 hours later
Low-Ogestrel®	30 mcg EE	0.3 mg N	4 white tablets, repeat 12 hours later
Nordette®	30 mcg EE	0.15 mg L	4 light orange tablets, repeat 12 hours later
Ogestrel 0.5/50®	50 mcg EE	0.5 mg N	2 white tablets, repeat 12 hours later
Ovral®	50 mcg EE	0.5 mg N	2 white tablets, repeat 12 hours later
Portia®	30 mcg EE	0.15 mg L	4 pink tablets, repeat 12 hours later
Seasonale®	30 mcg EE	0.15 mg L	4 pink tablets, repeat 12 hours later
Tri-Levlen®	30 mcg EE	0.125 mg L	4 light yellow tablets, repeat 12 hours later
Triphasil®	30 mcg EE	0.125 mg L	4 light yellow tablets, repeat 12 hours later
Trivora®	30 mcg EE	0.125 mg L	4 pink tablets, repeat 12 hours later
Progestin-only regimen			
Ovrette®	N/A	0.075 mg N	20 yellow tablets x 1 dose
Plan B®	N/A	0.75 mg L	2 tablets x 1 dose; or 1 tablet and repeat 12 hours later

EE = ethinyl estradiol, L = levonorgestrel, N = norgestrel

Table 2 – Is your patient a candidate for EC?

- CONFIRM unprotected intercourse within the last 72 hours (120 hours for progestin-only regimen)
- ASSESS history of migraine or Deep vein thrombosis/pulmonary embolism (DVT/PE)
    - If yes, AVOID Yuzpe method, may use progestin-only method
- COUNSEL:
    - Appropriate dosing of EC pills
    - Potential side effects (e.g., use of an antiemetic with Yuzpe method)
- INFORM woman to take pregnancy test if menses has not returned within 3 weeks of EC use
- Since EC does not protect against sexually transmitted infections (STI), consider REFERRAL to medical care for follow-up STI screening and long-term contraceptive planning

---

[1] Moos MK. Unintended Pregnancies: A Call for Nursing Action. *Am J Maternal Child Nurs* 2003;28(1):24-30.
[2] Croxatto HB, Ortiz ME, Müller AL. Mechanisms of action of emergency contraception. *Steroids* 2003; 68:1095-98.
[3] Hertzen H, Piaggio G, Ding J, et.al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 2002;360:1803-10.
[4] Managing Contraception 2004-4005. Accessed December 30, 2004 at http://www.managingcontraception.com/managingcontraception.pdf
[5] Wells ES, Hutchings J, Gardner JS, et.al. Using pharmacies in Washington State to expand access to emergency contraception. *Family Planning Perspectives* 1998;30:288-90.

Editor's Note: The MPhA House of Delegates has passed a resolution on emergency contraception as stated below. It is the only position the Association has taken.

BE IT RESOLVED THAT: The Maryland Pharmacists Association recognizes the public health issue of emergency contraception and the need for expanded access provided by pharmacists voluntary participation through completion of an emergency contraception training program and a physician/pharmacist protocol agreement, and

BE IT FURTHER RESOLVED THAT: The Maryland Pharmacists Association supports keeping medications used for emergency contraception as prescription-only.

PHARMACIST

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Dave Geoghegan
P.O. Box 177
Kingsville, MD 21087
410-592-9856
dave.geoghegan@phmic.com

Continuing Education for Pharmacists

Volume XXII, No. 3

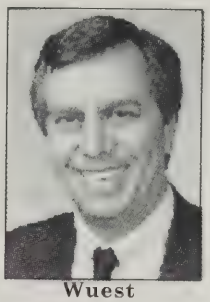
Management of Psoriasis: Focus on Raptiva

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Gossel



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Goals. The goals of this lesson are to provide background information on psoriasis and review the newest drug, Raptiva (efalizumab), approved for its treatment.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. explain the etiology and incidence of psoriasis;
2. identify factors associated with its onset;
3. identify the pharmacologic classification and list therapeutic considerations for efalizumab; and
4. select from a list, the indication, mechanism of action, adverse effects and toxicities, drug interactions, and benefits and limitations of efalizumab.

Psoriasis affects 1 to 3 percent of the world's population. Although distressing to the victim, this chronic inflammatory skin disorder is rarely life-threatening.

Psoriasis has an unpredictable course; after onset, it may remain confined to an elbow, knee, the scalp, face or nails, or become generalized over much of the body's surface. It occurs rarely on mucosal surfaces, and is not contagious. Silvery scales, which can be easily removed by picking or rubbing with a rough cloth, overlay the lesions. If removed, the scales become brittle and powdery. Lesions may appear at any age, but the average age of onset is 28 years. When psoriasis is diagnosed before age 15, it often involves a greater proportion of body surface, and these patients are less responsive to therapy. Slightly more common in women than men, psoriasis may appear for the first time following childbirth.

A positive family history of the disease is shared by over 50 percent of psoriasis sufferers. If one parent is affected, offspring have a 25 percent greater chance of developing psoriasis; if both parents are affected, the probability increases to 65 percent. Ninety-eight percent of all psoriasis suffers are Caucasian, but the disease occurs in all races. Psoriasis shows no preference for socioeconomic class or geographic area of residence.

Chronic itching can be severe in some patients with psoriasis. When scales are removed by scratching, rubbing, or picking, a salmon-pink to glassy-red lesion is exposed. The underlying skin may bleed from small points (Auspitz sign). Some patients suffer from chronic scaling, itching and discomfort; others, however, may remain asymptomatic for long stretches, followed by periods of intermittent flare-ups. Seventy-five percent of people with moderate to severe psoriasis report that their disease has a moderate to large negative impact on their everyday lives. The National Psoriasis Foundation estimates that the overall cost to treating psoriasis in the U.S. may exceed $3 billion annually.

Plaque psoriasis (psoriasis vulgaris), the most common type of psoriasis, is characterized by stable, slow-developing, usually symmetrical lesions (plaques) appearing typically on the elbows, knees, gluteal region (area of the buttocks) cleft, and scalp. Plaques may wax and wane but tend to be chronic.

Inverse psoriasis is characterized by sharply demarcated plaques in the intertriginous regions (areas of skinfolds), including under the arms, groin, submammary region, and navel. These lesions may also appear on palms, soles, and scalp.

Eruptive psoriasis (guttate psoriasis) develops in patients who lack a prior history of psoriasis or in those with chronic plaque psoriasis. It is most common in children and young adults. Patients usually display multiple small, erythematous, teardrop-shaped lesions that later coalesce into larger plaques. Scaling papules may be precipitated by a variety of conditions, including upper respiratory tract infection with beta-hemolytic streptococci.

Nummular psoriasis presents as lesions that coalesce into large, usually symmetrical, coin-

Table 1
Provoking Factors in Psoriasis

- Contact sports
- Dermal lesions (e.g., cuts, burns, sunburns)
- Systemic infections
- Drugs (e.g., antimalarials, lithium, certain beta-adrenergic blockers, clonidine, potassium iodide, NSAIDs, gold salts)
- Endocrine (e.g., psoriasis can improve or worsen during pregnancy and can flare with menopause)
- Immunologic mechanisms
- Obesity
- Psychological stress
- Alcohol
- Climate change
- Sunlight* and weather extremes
- Low humidity

*Exposure to moderate amounts of sunlight is associated with improvement of psoriasis. Excessive exposure or sunburn is correlated with psoriatic flares.

shaped masses. Appearing predominantly on the elbows, knees and lower back, these lesions do not cause significant itching, but scratching the surface of the plaque produces a waxy trail.

Etiology and Pathogenesis
The etiology of psoriasis is poorly understood, perhaps in part because the lack of a reliable animal model has impeded research. Psoriasis is characterized by alterations in the epidermis that permit rapid turnover of cells and inflammation of underlying capillaries, which culminate in rapid epidermal cell growth. Patients with psoriasis are more intolerant to cold weather than normal due to increased vasodilation and capillary proliferation, which promote loss of body heat.

With normal wear and tear of skin and replacement of new cells from underneath, the outermost dead cells are shed continually. The process that normally requires three to four weeks to complete may be shortened to three to four days in psoriasis patients. Accelerated epidermal proliferation is a hallmark of psoriasis. The rapid turnover of keratinocytes causes both viable and dead cells to accumulate on the skin's surface forming the characteristically thickened, scaly, silvery patches.

A key point in its etiology seems to be an altered immune function. Immunoglobulin G (IgG) can be detected in psoriatic lesions. One theory is that psoriasis patients cannot form sufficient T-suppressor cells so antibodies form against dermal antigens to promote formation of antigen-antibody complexes and inflammatory lesions.

Some known triggers of psoriasis are listed in Table 1. The Koebner phenomenon (isomorphic phenomenon) occurs when lesions develop on otherwise healthy skin at sites of severe injury (e.g., following cutting or scratching the skin, acute sunburn). This feature of psoriasis appears in 10 to 40 percent of patients and helps distinguish it from other pathologies. The relationship between trauma and subsequent appearance of lesions, usually within two to 18 days of the initial injury, is unclear. Patients should be advised to avoid injury or trauma to their skin, refrain from scratching, rubbing, or picking at the scales, and not apply adhesive tape over lesions.

Complications are uncommon; however, infection has resulted from over-ambitious therapy with corticosteroids applied under occlusive wrappings. Unrelenting itching from excessive scratching, sensitization to topically applied agents, and pus formation may also occur.

Arthritis symptoms are estimated to occur in 10 to 15 percent of patients and can be severe. Classically, the distal interphalangeal joints (i.e., of the fingers or toes) and adjacent nails are affected. Knees, elbows, wrists, and ankles may also be involved.

Differential Assessment
Psoriasis may be mistaken for seborrheic dermatitis and severe dandruff. Cradle cap is a form of seborrheic dermatitis that affects infants and may also be misdiagnosed as psoriasis. Certain features of each disorder permit a reliable differential assessment (Table 2). This is important since psoriasis requires a different therapeutic approach than dandruff or seborrheic dermatitis. Assessment may be aided by examining the fingernails and toenails for abnormal growth of nail plates and keratin accumulation under the nails with psoriasis. This produces distorted, thick, opaque, crumbly nails that may show pits and ridges. The nail may separate from its bed and be lost completely. Nail changes are noted in about half of all psoriasis sufferers. These changes are suggestive but not entirely diagnostic of psoriasis.

Management
There is no cure for psoriasis at present, only suppressive therapy. The goal of therapy is to decrease epidermal proliferation and dermal inflammation. Treatment depends on the type, location, and extent of disease. Regular use of appropriate medications can help control symptoms. Since psoriasis causes the barrier that normally prevents drug penetration into the skin to be disrupted, psoriatic skin may be more permeable than normal skin to many medications. In early treatment, patients may respond rapidly to a topical agent, with improvement slowing over time as the skin's barrier improves.

Raptiva (efalizumab)
Efalizumab is the newest therapy approved for treatment of psoriasis. It is a humanized immunosuppressive monoclonal antibody obtained by recombinant DNA technology that binds to human CD11a. CD11a is the alpha subunit of leukocyte function antigen-1 (LFA-1). LFA-1 is expressed on all leukocytes, and decreases cell surface expression of CD11a. Efalizumab inhibits the binding of LFA-1 to intercellular adhesion molecule-1 (ICAM-1), thereby inhibiting adhesion of leukocytes to other cells. The

Table 2
Differentiating Psoriasis from Other Skin Disorders

Characteristc	Psoriasis	Dandruff	Cradle Cap	Seborrheic Dermatitis
Site	Scalp & body	Scalp	Scalp	Scalp, face, body
Borders	Very sharp	Indistinct	Indistinct	Indistinct
Inflammation	Yes	No	Yes	Yes
Appearance of scales	Silvery scales that flake off in layers	Dry, grayish-white	Yellowish-brown, greasy	Greasy
Age at onset	Young adulthood usually, but can occur at any age	Puberty	1-2 weeks after birth, up to end of infancy	Puberty
Itching	Variable	Variable	Not known	Usual
External factors that worsen condition	Stress, mechanical irritation	Cold weather	Improper cleaning	Stress, poor health
Rate of epidermal turnover	Greatly increased over the norm (10-20X)	Twice the norm	Not demonstrated	More than twice the norm
Duration	Can persist for life; exacerbations & remissions	Can persist for life, diminishing in middle & old age	Usually clears in 3-4 weeks; can last up to 2 months	Can persist for life; frequent exacerbations & remissions

interaction between LFA-1 and ICAM-1 initiates and maintains multiple biological processes, including activation of T lymphocytes, adhesion of T lymphocytes to endothelial cells, and migration of T lymphocytes to sites of inflammation including psoriatic skin. Activation of lymphocytes and their migration to skin is a prime function in the pathology of chronic plaque psoriasis. In psoriatic skin, ICAM-1 cell surface expression is upregulated on endothelium and keratinocytes. As a side note, CD11a is also expressed on the surface of B lymphocytes, monocytes, neutrophils, natural killer cells, and other leukocytes. It is, therefore, feasible that efalizumab affects the activation, adhesion, migration, and count from cells other than T lymphocytes.

Efalizumab was evaluated in a series of four randomized, double-blind, placebo-controlled studies in adults with stable plaque psoriasis present for >6 months. All patients had a minimum body surface area involvement of psoriasis of 10 percent and were candidates for, or had previously received, systemic therapy or phototherapy (PUVA) for their disorder. Patients with clinically significant flares and patients with lesions other than plaque psoriasis were excluded from the trials. Patients received doses of 1 mg/kg SC or 2 mg/kg SC of efalizumab or placebo once a week for 12 weeks; patients receiving efalizumab were administered 0.7 mg/kg as the first dose. Patients could receive concomitant low-potency topical steroids as needed, but no other concomitant psoriasis therapies were permitted.

Patients were evaluated using a standardized index that took into consideration both the fraction of body surface area affected and the nature and severity of the psoriatic changes within the affected regions. Compared with placebo, more patients assigned to efalizumab experienced a significant improvement in their condition than those receiving placebo. The efalizumab 2 mg/kg dose was not superior to efalizumab 1 mg/kg.

Adverse Effects. The most common adverse reaction associated with efalizumab noted in clinical trials was a reaction complex to the first dose that included headache, chills, fever, nausea, and muscle pain (myalgia). These reactions were largely mild to moderate in severity when the first dose of Raptiva was limited to 0.7 mg/kg. Twenty-nine percent of patients treated with Raptiva 1 mg/kg developed one or more of these symptoms following the first dose compared with 15 percent of patients receiving placebo. After the third dose, the numbers had dropped to 4 percent and 3 percent of patients receiving Raptiva 1 mg/kg and placebo, respectively. Fewer than 1 percent of patients discontinued drug treatment

because of the reaction complex. Other adverse events (as percent) resulting in discontinuation of Raptiva treatment were worsening of psoriasis (0.6), pain (0.4), arthritis (0.4), and arthralgia (0.3).

Additional adverse events have been observed. The most notable during clinical trials were serious infections, malignancies, thrombocytopenia and psoriasis worsening and variants.

Raptiva has the potential to increase the risk of infection and reactive latent, chronic infections because it is an immunosuppressant. The drug should not be administered when clinically significant infection is present. Caution is advised when the use of Raptiva is considered in patients with a chronic infection or history of recurrent infections. The drug should be discontinued if a patient develops a serious infection.

Of 2762 psoriasis patients who received Raptiva at any dose, 31 patients were determined to have developed 37 malignancies. The malignancies included non-melanoma skin cancer, non-cutaneous solid tumors, Hodgkin's lymphoma and non-Hodgkin's lymphoma, and malignant melanoma. The occurrence and incidence of non-cutaneous solid tumors and malignant melanoma were within the range anticipated for the general population.

Platelet counts dropped to <52,000 cells per μL in 0.3 percent of Raptiva-treated patients during clinical trials compared with no cases among those on placebo. Thrombocytopenia resolved in the patients receiving adequate follow-up. Assessment of platelet counts with observation for signs and symptoms of thrombocytopenia (e.g., bleeding from the gums, bruising, or multiple petechiae [pinpoint hemorrhages] on the lower legs especially) is recommended during treatment with Raptiva and the drug should be discontinued if thrombocytopenia develops.

Symptomology of psoriasis can worsen during or following discontinuation of Raptiva. These events took the form of psoriatic erythroderma (abnormal redness of the skin) or pustular psoriasis in some patients, and some required hospitalization and alternative antipsoriatic therapy.

The safety and efficacy of vaccines administered to patients being treated with Raptiva have not been adequately evaluated. In one small investigation with Raptiva administered IV, a single dose of 0.3 mg/kg (0.3 mg/kg IV has similar pharmacodynamic activity as 1 mg/kg SC) given before primary immunization with a vaccine decreased the secondary immune response; a dose of 1 mg/kg almost completely eliminated it.

Drug Interactions. Formal studies have not been conducted with Raptiva to evaluate the possibility of drug interactions. Raptiva should not be administered with other immunosuppressive drugs, and acellular, live and live-attenuated vaccines should not be used concurrently with Raptiva treatment.

Indications and Uses. Raptiva is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is the first biologic therapy designed specifically for continuous control of the disease.

Dosage and Administration. The recommended initial dose of Raptiva is 0.7 mg/kg SC followed with weekly doses of 1 mg/kg SC. A maximum single dose should not exceed a total of 200 mg. Raptiva is to be administered under the guidance and supervision of a physician; if appropriate, patients may self-inject Raptiva after proper training.

Patients should be told that their physician may monitor platelet counts during therapy. They should be advised to seek medical attention at once if they develop any of the signs and symptoms (discussed earlier in this lesson) associated with severe thrombocytopenia. Patients should understand that Raptiva is an immunosuppressant that may increase their chances of developing an infection or a malignancy. They should be advised to call the prescribing physician promptly if they develop any new signs of, or receive a new diagnosis of, infection or malignancy while undergoing treatment with Raptiva.

It is not known whether Raptiva can cause fetal harm when given to pregnant women. Women should be advised to contact their physician if they become pregnant while taking Raptiva or within six weeks of discontinuing it.

Patients and/or their caregivers should be instructed how to avoid infection and how to measure the correct dose. They should also receive the manufacturer's Raptiva Patient Package Insert and be instructed to read it carefully. In addition, patients should be instructed not to reuse syringes and needles and how to dispose of them properly.

Raptiva is supplied as a lyophilized, sterile powder that when reconstituted provides 125 mg of efalizumab per single-use vial. Vials of lyophilized powder must be refrigerated at 36-46°F and be protected from exposure to light.

Continuing Education Quiz

This month's questions are taken from the article on "Management of Psoriasis: Focus on Raptiva". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 3/15/07. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-04-003-H01.

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1. All of the following statements about psoriasis are true EXCEPT:
   a. it is contagious.
   b. it occurs rarely on mucosal surfaces.
   c. it is rarely life-threatening.
   d. it can be confined to one area or generalized over the body.

2. The average age of onset of psoriasis is:
   a. 14.
   b. 28.
   c. 42.
   d. 56.

3. Psoriasis is most prevalent in:
   a. Asians.
   b. African-Americans.
   c. Caucasians.
   d. Polynesians.

4. When psoriasis affects intertriginous regions, it refers to areas of:
   a. exposed skin.
   b. nails.
   c. scalp.
   d. skinfolds.

5. The hallmark of psoriasis is:
   a. accelerated epidermal proliferation.
   b. excessive formation of dihydrotestosterone.
   c. infection by tinea versicolor.
   d. malfunction of the sebaceous glands.

6. Which of the following statements is true?
   a. Treatment of psoriasis and seborrheic dermatitis is the same.
   b. Borders of psoriatic lesions are very sharp rather than indistinct.
   c. Psoriasis affects the body, but not the scalp.
   d. Cradle cap is a form of psoriasis.

7. Which of the following best describes the appearance of psoriatic scales?
   a. Grayish-white
   b. Greasy
   c. Silvery
   d. Yellowish-brown

8. Raptiva is a(n):
   a. anti-epithelian cell stimulant factor.
   b. enzyme inhibitor.
   c. keratin stem cell inhibitor.
   d. monoclonal antibody.

9. Raptiva is currently approved to be administered:
   a. intravenously.
   b. orally.
   c. subcutaneously.
   d. topically.

10. Prior to administration, raptiva must be stored:
   a. at room temperature.
   b. under refrigeration.

MPhA Member Sam Lichter is participating in a study conducted by the University of Maryland, School of Pharmacy. The study is a survey on pharmacists' knowledge and attitudes of buprenorphine treatment and the Drug Addiction Treatment Act of 2000.

Pharmacist Samuel Lichter hasn't dispensed buprenorphine (Suboxone® or Subutex®) yet, but his pharmacy is located just 14 miles from downtown Baltimore, a city with an estimated 50,000-55,000 illicit drug users, most of them using heroin. When the U.S. Congress passed the Drug Addiction Treatment Act in 2000 they authorized doctors to prescribe, and pharmacists to dispense these medications for community based opioid addiction treatment. In the Baltimore area there are an estimated 75 physicians authorized to prescribe buprenorphine for opioid addiction treatment.

Sam participated in a projected sponsored by the Robert Wood Johnson Foundation that is being carried out by the Office of Substance Abuse Studies at the University of Maryland, School of Pharmacy. The project seeks to determine how pharmacists' knowledge of the new law affects their dispensing of these new addiction pharmacotherapies. Sam is shown here accepting a certificate acknowledging his $200 prize for winning a lottery among those pharmacists who returned a survey about buprenorphine treatment. Early next year he will receive an educational C.D. and later a followup survey. Another lottery will take place to pick a winner from among those who return the survey, and Sam may win another $200 prize. Who know? Lightening may strike twice in the same place.

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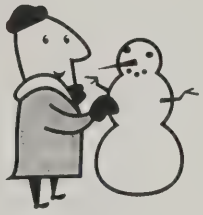

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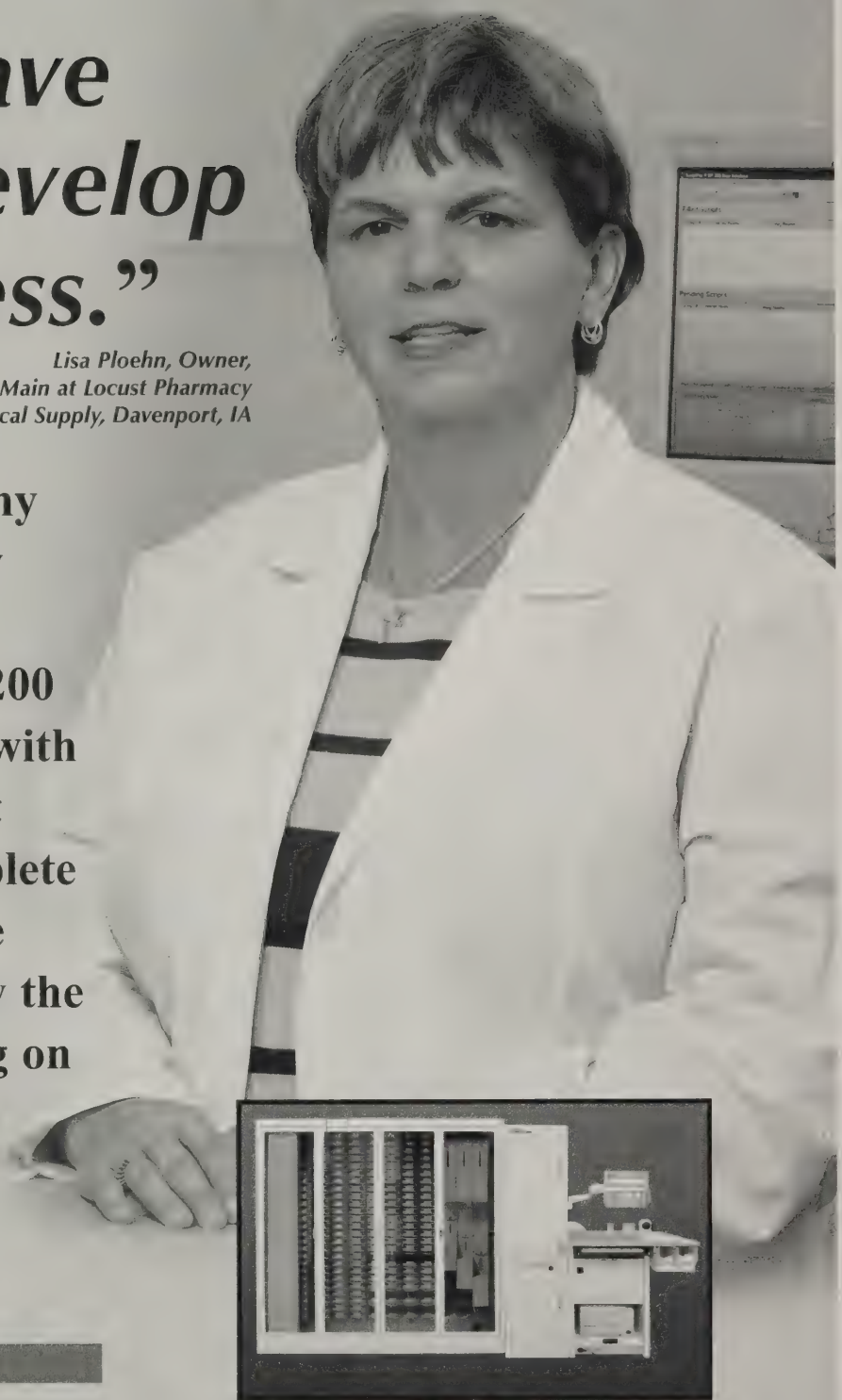

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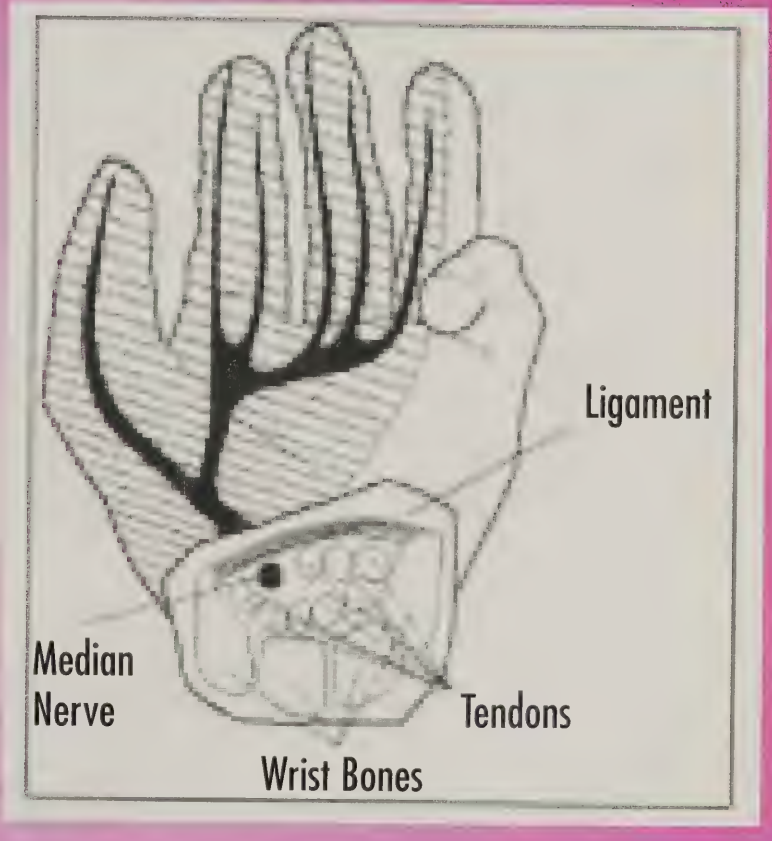

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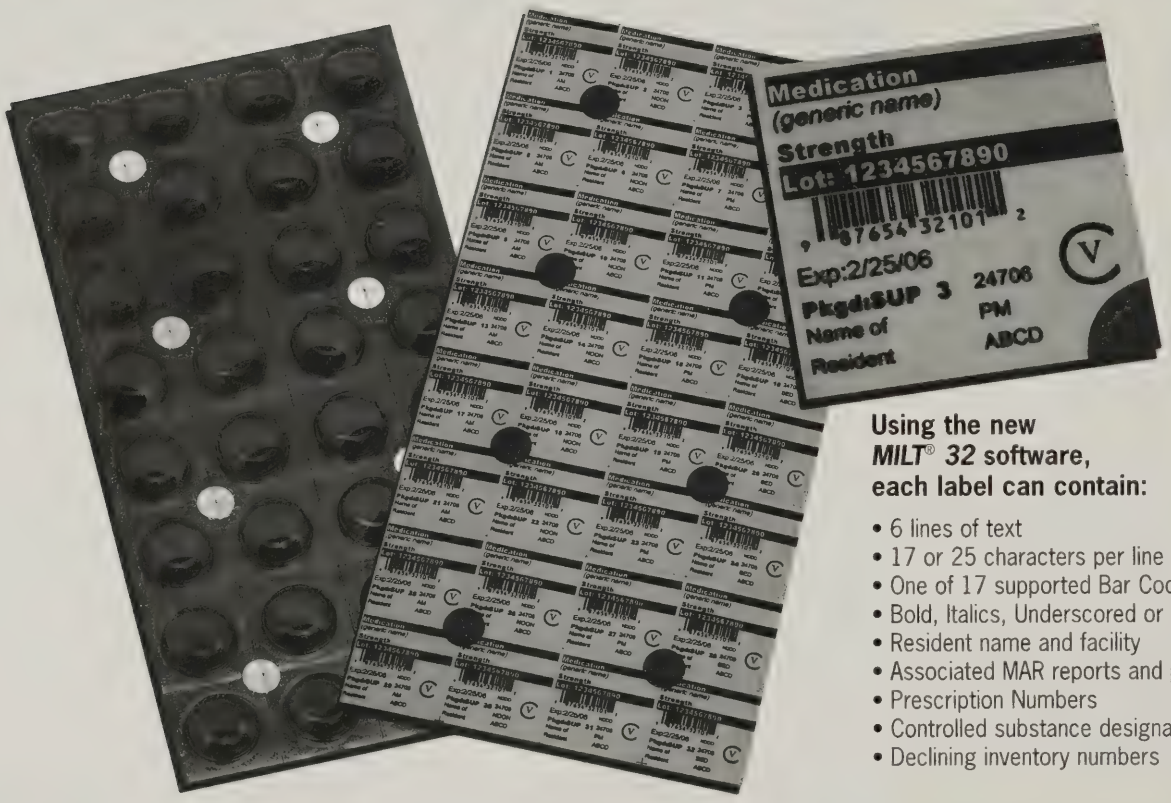

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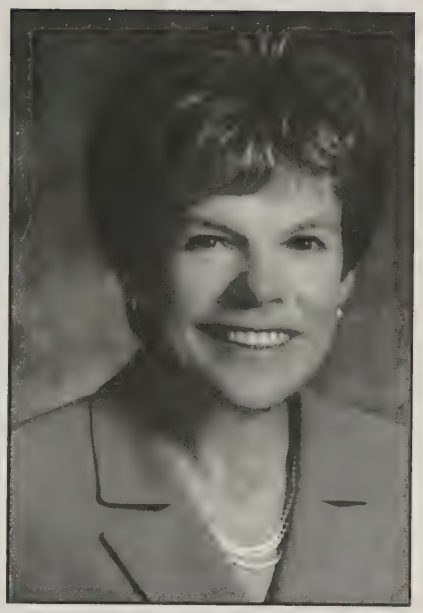
I imagine that each MPhA president who has contemplated his or her final commentary seeks a compelling topic. This article is adapted from my remarks to the University of Maryland School of Pharmacy Class of 2005 at the Alumni Association Banquet May 19, 2005. It was a distinctive moment as I presented the invitation for MPhA membership to them as both the MPhA president and as a faculty member.



Cynthia Boyle, Pharm.D.
President

Surviving and Thriving as a Pharmacist

Surviving

This word has new meaning with the success of the reality show *Survivor*. Contestants who overcome the hardships concentrate on the basics for survival. What are those basics for pharmacists' survival after graduation? I would include:

- License to practice
- Liability insurance
- Continuing education

With these three necessary survival tools, a pharmacist can get a job, earn a living, and survive. Yet, instead of getting voted off an island as happens to individuals on *Survivor*, many pharmacists practice pharmacy on an island, at a given location or within a particular company. It is difficult to survive, much less thrive, in isolation.

Thriving

Beyond survival, what are the tools which promote professional satisfaction and "thrival"? What is unique about pharmacists who look forward to practice every day, and how are they immune from professional burn-out due to daily challenges and difficulties. I believe they prosper by:

- Maintaining state and national professional organization membership,
- Promoting health-oriented practice, and
- Harnessing dissatisfaction.

State and National Professional Organization Membership

I have long been a member of MPhA and APhA. At one point, I let my national membership lapse, but I now believe that was short-sighted economy. Even at those times I could not participate in person, I benefited from the timely communications and the professional staff members who were working full-time on issues and opportunities for pharmacists. This year I turned to APhA's web-based resources when I was asked to comment on drug importation. I value the quality publications which are regularly delivered to my home.

More recently I have experienced APhA in a more significant role as MPhA president. In some ways, the 2005 APhA convention was an "Iowa" event. Newly-installed APhA President and community pharmacy owner Gene Lutz, Remington Medal recipient Robert Osterhaus, and Matt Osterhaus, owner of Osterhaus Pharmacy and Community and Ambulatory Practice Distinguished Achievement Award honoree, are all from Iowa. Notably, Gene Lutz referred to the need for the national organization to collaborate better with state organizations, just as we expect collaborative practice among health practitioners. I admire Bob Osterhaus as a pharmacist, a legislator, and a leader. He often says, "If it is good for the patient, it is good for pharmacy."

State presidents participate in many ways during the national APhA convention.

- Many of us served as delegates for our states in the House of Delegates.
- We were also invited to participate in a Medicare forum with the executive directors of the state associations where we heard CMS administrator Mark B. McClellan, MD, PhD, share his vision for transforming Medicare into a program that provides "affordable, prevention-oriented, personalized, high-quality care and that gives patients the information and support they need to be educated health care consumers. Pharmacists will play a central role."
- We were recognized at the opening general session and invited to the President's reception which paid tribute to Dan Herbert who died last year while serving as APhA president.
- There was also a State Officers' Forum where common state concerns such as legislative initiatives, membership involvement, and organizational structure refinements were discussed. I also met Lori Bickel who is new to the APhA state liaison role that Lisa Geiger had served.
- The elegant Leadership Dinner was a highlight that focused on the contributions of the state associations and need for national leaders. I sat next to COL Mike Heath who had received the APhA Distinguished Federal Pharmacist award, and I enjoyed his insights about his 30 years as a commissioned officer and pharmacist in the U.S. Army.

If you aspire to run for MPhA president in the future, you can look forward to interacting with capable, accomplished people and to being treated very well at the annual APhA convention. I value my state and national memberships even more, and I encourage others to maintain those affiliations and networks which inspire ideas and promote professional satisfaction and growth.

Tip #1: Treat your membership renewal as you would your license renewal.

Health-Oriented Practice

I recently attended the "Art of Advocacy" workshop sponsored by Research! America (http://www.researchamerica.org) at the Johns Hopkins Bloomberg School of Public Health. I feel that pharmacists through direct patient care practice and volunteer activities support wellness and disease prevention. However, I was astounded that our profession, as the most accessible healthcare profession, was not well-represented among the 500 member organizations' health outreach programs.

It is impossible to condense a workshop into a few sentences, but there is one simple step which pharmacists can implement toward a health-oriented practice. Use succinct, positive health messages. Many student pharmacists in admissions interviews say they want "to help people". After graduation and in practice, practitioners should be able to explain "how they want to help people."

Can you express in no more than three simple, positive sentences what you do? You will need to practice those two or three sentences for responses to patients, the media, or elected officials. Some examples are:

I protect your health.
I promote the best use of medicines.
I manage medication systems for your safety.
I teach student pharmacists to improve your health.

Now add a "how" statement to explain the first. Examples would be:

I protect your health by monitoring for drug interactions.
I promote the best use of medicines by working with your other healthcare providers.
I manage medication systems for your safety by collaborating with the Institute for Safe Medication Practices.
I teach student pharmacists to improve your health by keeping current on health advances and promoting professionalism.

(***Continued on page 11***)

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Tour highlights:

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- An advocacy toolkit and website to help pharmacies conduct their own local outreach
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Log on to *www.KeepingPharmacyCarePersonal.com* to sign our petition and get more information.

Health Across America

Keeping Pharmacy Care Personal

This is the last of a four-part series on Drug Therapy Management. This series is intended to provide the community pharmacist with practical tips for improving care, generating revenue and increasing customer satisfaction.

"Drug Therapy Management Series: Part IV: Immunizing against Influenza"

Authors: Catherine E. Cooke, PharmD, BCPS, with assistance from Janice Kim and Reasol Agustin
Clinical Education Consultant, Pfizer, Inc.
Clinical Assistant Professor, University of Maryland School of Pharmacy

Nationwide, pharmacists are providing immunization services ranging from advocating increased awareness of the need for vaccines to administering immunizations. Currently, pharmacists in 43 states are authorized to administer immunizations.[1] In 2004, legislation modified the Maryland Pharmacy Act-Practice of Pharmacy to authorize pharmacists to administer the influenza vaccination.[2] However, before pharmacists can begin to immunize, regulations need to be finalized by the State Board of Pharmacy, the Board of Physician Quality Assurance and the Board of Nursing. By providing pharmacist-administered vaccinations in your pharmacy, you can expect healthier and more satisfied customers, increased revenue from administering vaccines and increased professional satisfaction.

Influenza is a preventable disease that can result in hospitalization or death. An average of 114,000 influenza related hospitalizations and 36,000 deaths occurs each year during influenza season.[3] Despite the serious consequences of influenza, many individuals fail to get vaccinated. For adults $\geq$ 65 years, the United States (U.S.) median annual influenza vaccination rate is 69.9%, comparable to Maryland's rate of 68.4%. However, in younger people, even those with high-risk conditions, the rate of influenza vaccination is much lower. For patients 18-64 years with diabetes or asthma, the U.S. median annual influenza administration rates are 34.0 – 49.0%, which is again comparable with Maryland's rate of 38.4-46.6%.[4] In an attempt to improve the health of the U.S. population, Healthy People 2010 has goals of achieving influenza vaccination rates of 90% for people $\geq$ 65 years or institutionalized and 60% for people 18-64 years.[5]

One of the solutions to improve rates for influenza vaccination is to provide immunizations in your pharmacy. Several studies have demonstrated that pharmacist-administered vaccines improve vaccination rates. In one study, influenza vaccination rates were significantly improved for patients $\geq$ 65 years in states where pharmacists were able to administer vaccines compared with states where pharmacists did not have those privileges.[6] In another study, surveyed patients reported that it was more convenient to receive an immunization outside a physician's office. In addition, this survey documented that adults were more supportive of receiving immunizations from non-physicians in non-traditional settings compared with parents of pediatric patients.[7]

There is also greater benefit when pharmacists administer immunizations compared with hiring a nurse to administer vaccines on-site in the pharmacy. One study compared the rate of influenza vaccination in Washington State pharmacies, a state where pharmacists administered vaccines, and Oregon pharmacies, a state where pharmacists, at the time of the study, were not able to administer vaccines. Washington State pharmacies were able to immunize eight times more patients than Oregon pharmacies.[8]

Influenza is the most common pharmacist-administered vaccine,[9] with immunization recommended during October and November of each year. Earlier October dates should focus primarily on persons aged $\geq$50 years and people at high risk of influenza-related complications.[3] Currently, there are two vaccines available, inactivated influenza vaccine (Flushield®, Fluzone®, Fluvirin®), which is given via the intramuscular (IM) route and a live, attenuated influenza vaccine (LAIV) (Flumist®), which is administered intranasally. Table 1 lists candidates who should be targeted to receive the influenza vaccine. While anyone can receive the inactivated influenza vaccine, the LAIV is only indicated for healthy people ages 5-49 years who are not contacts of severely immunosuppressed persons. The inactivated influenza vaccine and the LAIV are both contraindicated in patients with a hypersensitivity to egg or egg-containing products or a hypersensitivity to any components included in the vaccine. There is one additional contraindication specific to inactivated influenza vaccine, which includes patients with moderate to severe acute febrile illness. Specific contraindications to LAIV include: patients with immunodeficiency

disease or those receiving immunosuppressive therapies, children or adolescents (5-17 years) receiving aspirin or aspirin-containing therapy, or patients with a history of Guillain-Barre syndrome.

Additional resources about administering the influenza vaccine such as dosing, drug interactions, patient information, etc. can be found in Table 2.

Vaccine administration in the community pharmacy setting can be beneficial for both patients and providers. For patients, community pharmacies are more convenient than physician office practices because of extended hours, locations in patients' neighborhoods and less out-of-pocket expense. For immunization providers, the benefits include increased profitability through increased prescription volume and store traffic, improved relationships with other health care providers, and increased satisfaction for the pharmacists that participated.[10,11,12]

Many patients who desperately need the influenza vaccine in Maryland are not receiving it. Pharmacists can provide immunization services to their customers to assist in achieving the Healthy People 2010 immunization goals. Along with improved patient care, pharmacists are able to improve customer satisfaction and revenue for their pharmacies.

Table 1 – Target Groups for Influenza Vaccination[3]

1. **Persons at increased risk for complications**
   - Persons aged ≥65 years;
   - Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
   - Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
   - Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]);
   - Children and adolescents (aged 6 months-18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza infection;
   - Women who will be pregnant during the influenza season; and
   - Children aged 6-23 months.

2. **Persons aged 50-64 years**

3. **Persons who can transmit influenza to those at high risk**
   - Physicians, nurses, and other personnel in both hospital and outpatient-care settings, including medical emergency response workers (e.g., paramedics and emergency medical technicians);
   - Employees of nursing homes and chronic-care facilities who have contact with patients or residents;
   - Employees of assisted living and other residences for persons in groups at high risk;
   - Persons who provide home care to persons in groups at high risk; and
   - Household contacts (including children) of persons in groups at high risk.

Table 2 - Selected Resources for the Pharmacist (taken from Immunization Action Coalition, http://www.immunize.org/, Accessed 28 Feb. 2005)

"Communicating with Patients about Immunization" Source: National Network for Immunization Information
www.immunizationinfo.org/healthProfessionals/resource_kit.cfm

"Recommended Adult Immunization Schedule, United States" Source: Advisory Committee on Immunization Practices
www.cdc.gov/nip/recs/adult-schedule.pdf

"Recommended Childhood Immunization Schedule, United States" Source: Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics, and the American Academy of Family Physicians http://www.immunize.org/cdc/child-schedule.pdf

"How to Administer IM (Intramuscular) Injections" "How to Administer SC (Subcutaneous) Injections" Source: Adapted from the Minnesota Department of Health by the Immunization Action Coalition www.immunize.org/catg.d/p2020.pdf

Vaccine Adverse Event Report System (VAERS) The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration and the Centers for Disease Control and Prevention. VAERS collects and analyzes information from reports of adverse events (possible side effects) that occur after the administration of US licensed vaccines. Reports are welcome from all concerned individuals: patients, parents, health care providers, pharmacists and vaccine manufacturers. www.fda.gov/cber/vaers/vaers.htm

"Immunization Resource Directory" Source: Immunization Action Coalition www.immunize.org/resources

Education & Training for Immunization Providers Includes links to CDC's satellite broadcast schedule, self-study materials, on-site training information, and course materials and slides. **Source: Centers for Disease Control and Prevention** www.cdc.gov/nip/ed/default.htm

CDC's Immunization Information Hotline A toll-free telephone line health professionals can call to speak with an information specialist about vaccine questions. The hotline also answers consumer questions in English and Spanish. Hours: 8 am to 11 pm ET Monday to Friday. Call (800) 232-2522; for inquiries in Spanish, call (800) 232-0233.

[1] American Pharmacists Association Fact Sheet: States where pharmacists have the authority to immunize patients http://www.aphanet.org/pharmcare/immunofact.html (Accessed 28 February 2005)
[2] 2004 Regular Session bill information: Maryland Pharmacy Act – Practice of Pharmacy – Administration of the Influenza Vaccination http://mlis.state.md.us/2004rs/billfile/hb0384.htm (Accessed 28 February 2005)
[3] Centers for Disease Control and Prevention. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2004;53(RR-6):1-40.
[4] Influenza and Pneumococcal Vaccination Coverage Among Persons Aged ≥65 Years and Persons Aged 18-64 years with Diabetes or Asthma - United States, 2003. *MMWR* 2004;53:1007-12.
[5] US Public Health Service. Healthy People 2010: National health promotion and disease prevention objectives. Washington, DC: US Department of Health and Human Services, US Public Health Service; 2000
[6] Steyer TE, Ragucci KR, Pearson WS, et al. The role of pharmacists in the delivery of influenza vaccination. *Vaccine.* 2004;22:1001–6.
[7] Ernst ME, Bergus GR, Sorofman BA. Patients' acceptance of traditional and nontraditional immunization providers. *J Am Pharm Assoc* 2001;41:53-9.
[8] Grabenstein JD, Guess HA, Hartzema AG, et al. Effect of vaccination by community pharmacists among adult prescription recipients. *Med Care* 2001;39:340-8.
[9] Neuhauser MM, Wiley D, Simpson L, et al. Involvement of immunization-certified pharmacists with immunization activities. *Ann Pharmacother* 2004;38:226-31.
[10] Duvall, K. Community-based influenza immunization program. *US Pharm* 2005;2:55-9.
[11] Smith C. Pharmacy-based immunization. US Pharm 1999;24. http://www.uspharmacist.com/oldformat.asp?url=newlook/files/Feat/immune.cfm&pub_id=8&article_id=402 (Accessed 28 February 2005)
[12] Weitzel KW, Goode JV. Implementation of a pharmacy-based immunization program in a supermarket chain. *J Am Pharm Assoc* 2000;40:252-6.

Surviving and Thriving as a Pharmacist (*Continued from page 6*)
Language and purpose are important. For that reason, the Maryland Pharmacy Coalition adopted "Pharmacists for a Safe and Healthy Maryland" for the 2005 Legislative Day. I urge you to banish the phrase, "I am just a pharmacist," or ,"I fill prescriptions." Pay attention to potential health promotions, such as Get Fit Maryland (http://www.getfitmaryland.org/); and prepare, practice, and deliver your health-oriented goal message for your health-oriented practice responsibilities.

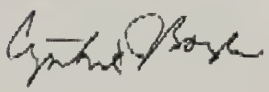
In developing a health-oriented practice, pharmacists need to put their own health and well-being on the list of priorities as well. We are sometimes better at giving health advice than following it, and we often take better care of our cars or pets than ourselves. Protect your health and replenish your reserves through activities which give you joy. A well-rested, healthy, and fulfilled pharmacist will be better prepared to make positive contributions for family members, public health, communities, and the profession.

Tip #2: Commit to participating in at least one well-planned health promotion yearly.

Dissatisfaction
You may be surprised that I have included dissatisfaction as a means of thriving as a pharmacist. Dissatisfaction by itself is a complaint. Dissatisfaction harnessed with creative ideas can become a solution. Dissatisfaction has served MPhA well this year. We were dissatisfied with the cumbersome size of the Board of Trustees and have drafted a constitution and bylaws revision to be considered by the membership. We were dissatisfied with communication and marketing and have worked to improve the effectiveness of both. Personally, I am dissatisfied with the number of new practitioners in the organization, and I am working with the Maryland Pharmacy Coalition to mentor and develop those future leaders.

Tip #3: Harness dissatisfaction to create solutions.

The legacy of leadership in MPhA has transcended 123 years. I have been honored to serve as the 120th president, and I have been fortunate to work with devoted officers and trustees, professional staff, and accomplished members. All of us congratulate the Class of 2005, and we look forward to sharing the profession with you.



Rx AND THE LAW

By Jill Flaherty, Pharm D.
and Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

ESTABLISHING SYSTEMS FOR PHARMACY DRUG WITHDRAWALS AND RECALLS

Vioxx, Cylert, phenylpropanolamine, Rezulin, Baycol, and Propulsid top the list of prominent drug products either recalled or voluntarily withdrawn from the marketplace within the past ten years. The recent Vioxx withdrawal has generated an unprecedented amount of publicity about drug product withdrawals and recalls.[1] It has also placed pharmacies and pharmacists in the spotlight as they address patient safety concerns and complaints.

Individual pharmacists and pharmacies may be subject to legal scrutiny for months and even years after a product has been removed from the market. This occurs because patients want assurance that they have not suffered damages as a result of a defective or dangerous product, that they are not inadvertently receiving old product formulations, and that their pharmacist is providing sufficient counseling and warnings regarding the product recall or withdrawal. Each of these patient concerns carries with it potential liability concerns for pharmacists.

How can pharmacies and individual pharmacists prevent their involvement in litigation related to product recalls or withdrawals? Where have pharmacists made errors in the past with drug recall and withdrawal procedures? Each of these questions can be answered by the following thorough evaluation of best practices for pharmacists properly executing a recall or withdrawal situation.

Pharmacists must achieve an actual understanding of the withdrawal and recall process before establishing systems to respond to such a situation. Then policies and procedures can be established and executed, documentation can occur and be maintained, and open lines of communication with patients, wholesalers, and manufacturers will follow.

It is crucial for pharmacists to have a good understanding of the process of product withdrawals and recalls. Because of the media attention and scrutiny focused on the Food and Drug Administration (FDA) and the product's manufacturer to determine the best way to protect the public from unsafe medications, patients will likely ask for clarification from their pharmacist. Thus pharmacists must be able to vocalize to patients the significance of and reasons for a withdrawal or recall. This is the first step a prudent pharmacist should take in establishing systems for drug withdrawals and recalls.

[1] http://www.merck.com/newsroom/vioxx_withdrawal

1. Understand the significance of and reasons for a drug withdrawal or recall.
2. Establish pharmacy policies and procedures for executing a drug withdrawal or recall if they do not currently exist.
3. Follow established policies and procedures.
4. Document actions taken and maintain records.

Most pharmacists look to the FDA for information regarding product recalls or withdrawals. Although the FDA may request a product recall or use statutory authority to remove a product from the market, these occur less frequently than manufacturer withdrawals. FDA requests for a recall occur only when a manufacturer is unwilling to remove a product without a written request from the FDA. Statutory authority for drug recalls and withdrawals exists only if the product is a medical device or a human tissue product that poses a risk to human health.[2] Most frequently, products are voluntarily removed due to a minor concern that is not subject to FDA legal action; the manufacturer then chooses to remove their product in order to make necessary adjustments.

Specific terminology exists for assessing the severity and significance of recalls. They can vary in severity from Class I (use of or exposure to the product is likely to cause serious adverse health effects or death) to Class III (use of or exposure to product is not likely to cause adverse health consequences).[3] An example of a Class I recall could include an IV product labeled as 10mg/ml, when it actually contains 100mg/ml. A Class III recall could be an oral liquid formulation with an off-taste compared to normal formulation; a slight variation exists in the product from which no likely harm will result.

Once a pharmacist is able to clearly and objectively communicate with patients regarding the withdrawal and recall process, they will more effectively be able to establish pharmacy policies and procedures for executing a drug recall if they do not currently exist. Most pharmacies will likely have existing policy and procedure for pharmacists to execute in such an event. It is vital for pharmacists to follow their established policies and procedures. The only situation worse than being unprepared to handle a drug recall is to have documented instructions on how to act and neglect to follow them.

Ideal policies and procedures will include the prompt removal and quarantine of product from pharmacy shelves and completed prescriptions until return or disposal procedures have been identified. This is vital to ensure that no further prescriptions for the product are filled for or dispensed to patients. The quarantined stock of the product should promptly be removed from the pharmacy. The removal of products should occur according to specified instructions provided by the FDA or manufacturer, according to product NDC number, lot number, and expiration date.

The pharmacy computer system must also be updated to mark or flag the product at hand to prevent reordering of the product or borrowing from other pharmacies. After completing the task of removing product from your pharmacy you want to be certain that the product is not returned to your stock. Therefore, all pharmacy staff must be notified of these actions immediately to prevent others from replenishing the product you have recently purged from the stock.

"If it wasn't documented, it wasn't done" is a phrase with which pharmacists are very familiar in practice. All actions taken within the pharmacy to remove withdrawn or recalled products must be documented and that documentation must be maintained by the pharmacy for future use to prove what actions were taken to protect patients from the identified product.

There are a variety of ways to adequately document these actions, including, but not limited to, maintaining a withdrawal and recall file within the pharmacy, utilizing a pharmacists journal to describe actions taken on specific dates, or file a more formal report with a manager or supervisor within a corporate office of the pharmacy. The imperative action is to first create documentation and then maintain such documentation in order to utilize it in the future to recall what actions were taken and by whom. Keep in mind that although you are able to recall actions taken for a few months or even a year, the details will at some point be forgotten. Documented records will provide sufficient evidence of your actions at a time when you may be unable to specifically remember the event or any actions taken. Achieving a thorough

[2] § 412and § 518 Food Drug and Cosmetic Act; § 351 Public Health Service Act
[3] http://www.fda.gov/oc/po/firmrecalls

understanding of the reasons for and severity of the withdrawal or recall, following policies and procedure, and documenting and maintaining records of actions taken will best protect a pharmacist from the legal scrutiny associated with product withdrawals and recalls. Pharmacists must recognize the significance of their actions in a withdrawal or recall situation, in order to effectively prevent future involvement in litigation related to recall and withdrawal events. Prudent behavior and business practices should adequately protect a pharmacist from increased legal scrutiny. However, the patient's rights and expectations should be the top priority; patients both expect and deserve a rapid response by pharmacists to remove unsafe products from their shelves in order to protect them from what may be a significant patient care concern.

©Jill Flaherty and Karen Peterson. Jill Flaherty is a Drake University Pharmacy graduate and is currently pursuing a Law Degree at Drake University in Des Moines, Iowa. Karen E. Peterson, R.Ph., J.D. is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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FDA BT RATING

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Important safety information: Istalol™ is contraindicated in patients with bronchial asthma, a history of bronchial asthma, severe COPD, sinus bradycardia, second- or third-degree atrioventricular block, overt cardiac failure, or cardiogenic shock.

The most frequently reported adverse event with Istalol™ was burning and stinging upon instillation (38%). The same adverse reactions found with systemic administration of beta-adrenergic–blocking agents may occur with topical ophthalmic administration. Because of the potential effects of beta-adrenergic–blocking agents on blood pressure and pulse, these agents should be used with caution in patients with cerebrovascular insufficiency.

Please see brief summary of prescribing information on following page.

1. FDA Orange Book 2004.

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ISTALOL (timolol maleate ophthalmic solution) 0.5%

Brief Summary of Prescribing Information

Sterile

INDICATIONS AND USAGE

ISTALOL ophthalmic solution is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

CONTRAINDICATIONS

ISTALOL is contraindicated in patients with (1) bronchial asthma; (2) a history of bronchial asthma; (3) severe chronic obstructive pulmonary disease **(see WARNINGS)**; (4) sinus bradycardia; (5) second or third degree atrioventricular block; (6) overt cardiac failure **(see WARNINGS)**; (7) cardiogenic shock; or (8) hypersensitivity to any component of this product.

WARNINGS

As with many topically applied ophthalmic drugs, this drug is absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported following systemic or ophthalmic administration of timolol maleate (see CONTRAINDICATIONS).

Cardiac Failure

Sympathetic stimulation may be essential for support of the circulation in individuals with diminished myocardial contractility, and its inhibition of beta-adrenergic receptor blockade may precipitate more severe failure.

In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of cardiac failure, ISTALOL should be discontinued.

Obstructive Pulmonary Disease

Patients with chronic obstructive pulmonary disease (e.g., chronic bronchitis, emphysema) of mild or moderate severity, bronchospastic disease, or a history of bronchospastic disease (other than bronchial asthma or a history of bronchial asthma, in which ISTALOL is contraindicated **[see CONTRAINDICATIONS]**) should, in general, not receive beta-blockers, including ISTALOL.

Major Surgery

The necessity or desirability of withdrawal of beta-adrenergic blocking agents prior to major surgery is controversial. Beta-adrenergic receptor blockade impairs the ability of the heart to respond to beta-adrenergically mediated reflex stimuli. This may augment the risk of general anesthesia in surgical procedures. Some patients receiving beta-adrenergic receptor blocking agents have experienced protracted severe hypotension during anesthesia. Difficulty in restarting and maintaining the heartbeat has also been reported. For these reasons, in patients undergoing elective surgery, some authorities recommend gradual withdrawal of beta-adrenergic receptor blocking agents. If necessary during surgery, the effects of beta adrenergic blocking agents may be reversed by sufficient doses of adrenergic agonists.

Diabetes Mellitus

Beta-adrenergic blocking agents should be administered with caution in patients subject to spontaneous hypoglycemia or to diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Beta-adrenergic receptor blocking agents may mask the signs and symptoms of acute hypoglycemia.

Thyrotoxicosis

Beta adrenergic blocking agents may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta-adrenergic blocking agents that might precipitate a thyroid storm.

PRECAUTIONS

General

Because of potential effects of beta-adrenergic blocking agents on blood pressure and pulse, these agents should be used with caution in patients with cerebrovascular insufficiency. If signs or symptoms suggesting reduced cerebral blood flow develop following initiation of therapy with ISTALOL, alternative therapy should be considered. There have been reports of bacterial keratitis associated with the use of multiple dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface **(see PRECAUTIONS, Information for Patients)**

Choroidal detachment after filtration procedures has been reported with the administration of aqueous suppressant therapy (e.g. timolol)

Angle-closure glaucoma: In patients with angle-closure glaucoma, the immediate objective of treatment is to reopen the angle. This requires constricting the pupil. Timolol maleate has little or no effect on the pupil. ISTALOL should not be used alone in the treatment of angle-closure glaucoma.

Anaphylaxis: While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge with such allergens. Such patients may be unresponsive to the usual doses of epinephrine used to treat anaphylactic reactions.

Muscle Weakness: Beta adrenergic blockade has been reported to potentiate muscle weakness consistent with certain myasthenic symptoms (e.g., diplopia, ptosis, and generalized weakness). Timolol has been reported rarely to increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.

Information for Patients

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

Patients should also be instructed that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions **(see PRECAUTIONS, General)**

Patients should also be advised that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

Patients with bronchial asthma, a history of bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, second or third degree atrioventricular block, or cardiac failure should be advised not to take this product **(see CONTRAINDICATIONS)**

Patients should be advised that ISTALOL contains benzalkonium chloride which may be absorbed by soft contact lenses. Contact lenses should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following ISTALOL administration.

Drug Interactions

Although ISTALOL used alone has little or no effect on pupil size, mydriasis resulting from concomitant therapy with ISTALOL and epinephrine has been reported occasionally.

Beta-adrenergic blocking agents: Patients who are receiving a beta-adrenergic blocking agent orally and ISTALOL should be observed for potential additive effects of beta-blockade, both systemic and on intraocular pressure. The concomitant use of two topical beta-adrenergic blocking agents is not recommended.

Calcium antagonists: Caution should be used in the coadministration of beta-adrenergic blocking agents, such as ISTALOL, and oral or intravenous calcium antagonists because of possible atrioventricular conduction disturbances, left ventricular failure, and hypotension. In patients with impaired cardiac function, coadministration should be avoided.

Catecholamine-depleting drugs: Close observation of the patient is recommended when a beta blocker is administered to patients receiving catecholamine-depleting drugs such as reserpine, because of possible additive effects and the production of hypotension and/or marked bradycardia, which may result in vertigo, syncope, or postural hypotension.

Digitalis and calcium antagonists: The concomitant use of beta-adrenergic blocking agents with digitalis and calcium antagonists may have additive effects in prolonging atrioventricular conduction time.

Quinidine: Potentiated systemic beta-blockade (e.g., decreased heart rate) has been reported during combined treatment with quinidine and timolol, possibly because quinidine inhibits the metabolism of timolol via the P-450 enzyme, CYP2D6.

Clonidine: Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. There have been no reports of exacerbation of rebound hypertension with ophthalmic timolol maleate.

Injectable epinephrine. **(see PRECAUTIONS, General, Anaphylaxis)**

Pregnancy

Teratogenic Effects—Pregnancy Category C. Teratogenicity studies with timolol in mice, rats, and rabbits at oral doses up to 50 mg/kg/day (7,000 times the systemic exposure following the maximum recommended human ophthalmic dose) demonstrated no evidence of fetal malformations. Although delayed fetal ossification was observed at this dose in rats, there were no adverse effects on postnatal development of offspring. Doses of 1000 mg/kg/day (142,000 times the systemic exposure following the maximum recommended human ophthalmic dose) were maternotoxic in mice and resulted in an increased number of fetal resorptions. Increased fetal resorptions were also seen in rabbits at doses of 14,000 times the systemic exposure following the maximum recommended human ophthalmic dose, in this case without apparent maternotoxicity.

There are no adequate and well-controlled studies in pregnant women. ISTALOL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Timolol maleate has been detected in human milk following oral and ophthalmic drug administration. Because of the potential for serious adverse reactions from ISTALOL in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

The most frequently reported adverse experiences have been burning and stinging upon instillation in 38% of patients treated with ISTALOL. Additional events reported with ISTALOL at a frequency of 4 to 10% include: blurred vision, cataract, conjunctival injection, headache, hypertension, infection, itching and decreased visual acuity. The following additional adverse experiences have been reported less frequently with ocular administration of this or other timolol maleate formulations:

BODY AS A WHOLE

Asthenia/fatigue and chest pain.

CARDIOVASCULAR

Bradycardia, arrhythmia, hypotension, syncope, heart block, cerebral vascular accident, cerebral ischemia, cardiac failure, worsening of angina pectoris, palpitation, cardiac arrest, pulmonary edema, edema, claudication, Raynaud's phenomenon, and cold hands and feet

DIGESTIVE

Nausea, diarrhea, dyspepsia, anorexia, and dry mouth.

IMMUNOLOGIC

Systemic lupus erythematosus.

NERVOUS SYSTEM/PSYCHIATRIC

Dizziness, increase in signs and symptoms of myasthenia gravis, paresthesia, somnolence, insomnia, nightmares, behavioral changes and psychic disturbances including depression, confusion, hallucinations, anxiety, disorientation, nervousness, and memory loss.

SKIN

Alopecia and psoriasiform rash or exacerbation of psoriasis.

HYPERSENSITIVITY

Signs and symptoms of systemic allergic reactions, including angioedema, urticaria, and localized and generalized rash.

RESPIRATORY

Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure, dyspnea, nasal congestion, cough and upper respiratory infections.

ENDOCRINE

Masked symptoms of hypoglycemia in diabetic patients (see WARNINGS).

SPECIAL SENSES

Signs and symptoms of ocular irritation including conjunctivitis, blepharitis, keratitis, ocular pain, discharge (e.g., crusting), foreign body sensation, itching and tearing, and dry eyes; ptosis; decreased corneal sensitivity; cystoid macular edema; visual disturbances including refractive changes and diplopia; pseudopemphigoid; choroidal detachment following filtration surgery **(see PRECAUTIONS, General)**; and tinnitus.

UROGENITAL

Retroperitoneal fibrosis, decreased libido, impotence, and Peyronie's disease.

The following additional adverse effects have been reported in clinical experience with ORAL timolol maleate or other ORAL beta-blocking agents and may be considered potential effects of ophthalmic timolol maleate: ALLERGIC: Erythematous rash, fever combined with aching and sore throat, laryngospasm with respiratory distress; BODY AS A WHOLE: Extremity pain, decreased exercise tolerance, weight loss; CARDIOVASCULAR: Worsening of arterial insufficiency, vasodilatation; DIGESTIVE: Gastrointestinal pain, hepatomegaly, vomiting, mesenteric arterial thrombosis, ischemic colitis; HEMATOLOGIC: Nonthrombocytopenic purpura; thrombocytopenic purpura, agranulocytosis; ENDOCRINE: Hyperglycemia, hypoglycemia; SKIN: Pruritus, skin irritation, increased pigmentation, sweating; MUSCULOSKELETAL: Arthralgia; NERVOUS SYSTEM/PSYCHIATRIC: Vertigo, local weakness, diminished concentration, reversible mental depression progressing to catatonia, an acute reversible syndrome characterized by disorientation for time and place, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics; RESPIRATORY: Rales, bronchial obstruction; UROGENITAL: Urination difficulties.

OVERDOSAGE

There have been reports of inadvertent overdosage with ISTALOL ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, shortness of breath, bradycardia, bronchospasm, and cardiac arrest **(see also ADVERSE REACTIONS)**

An in vitro hemodialysis study, using 14C timolol added to human plasma or whole blood, showed that timolol was readily dialyzed from these fluids; however, a study of patients with renal failure showed that timolol did not dialyze readily.

DOSAGE AND ADMINISTRATION

ISTALOL ophthalmic solution is available in a concentration of 0.5 percent. The starting dose is one drop of 0.5 percent ISTALOL in the affected eye(s) once a day in the AM. If the patient's intraocular pressure is not at a satisfactory level on this regimen, concomitant therapy with other agent(s) for lowering intraocular pressure can be instituted. The concomitant use of two topical beta-adrenergic blocking agents is not recommended **(see PRECAUTIONS, Drug Interactions, Beta-adrenergic blocking agents)**.

Storage

Store at 15-25°C (59-77°F)

Rx Only

Manufactured for: SENJU Pharmaceutical Co., Ltd., Osaka, Japan 541-0046
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Continuing Education for Pharmacists

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Carpal Tunnel Syndrome: Part 1: The Condition, Symptoms, and Risk Factors

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this two-part lesson series are to discuss carpal tunnel syndrome and provide information on its management with medical and nonmedical interventions.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. describe carpal tunnel syndrome, state suspected causes and/or factors that aggravate symptoms, and list individuals who are at risk for developing it;
2. identify anatomical and physiological considerations on the etiology and pathogenesis of carpal tunnel syndrome;
3. recognize specific symptoms and identify means of assessment for carpal tunnel syndrome; and
4. distinguish between carpal tunnel syndrome and other pathologies that may mimic it.

Gossel

Wuest

Carpal tunnel syndrome (CTS) is the most common peripheral neuropathy in the U.S., and a component of a group of pathologies described as repetitive motion injuries, overuse syndromes, chronic upper limb pain syndromes, and nerve entrapment disorder. CTS is a frequent cause of work disability and the most prevailing cause of nighttime hand discomfort and pain.

Little is known about its prevalence in the general population. One estimate places its incidence in the U.S. close to 3 percent of adults. Studies in workers representing specific high-risk occupations reveal that CTS occurs more often in certain specialized groups (Table 1) than the general population. For example, 62.5 percent of supermarket checkers surveyed reported symptoms of CTS. Approximately 7 percent of employees of an electronics manufacturing plant developed symptoms over four years. More than 14 percent of meat handlers developed symptoms over a 12-year period. Fifteen percent of workers, on average, in high-risk industries are affected annually.

Today, repetitive motion disorders, as a group, account for more than one-half of all occupational illnesses in the U.S. and the number appears to be increasing. A 1996 study revealed the average total cost for bilateral CTS that required surgery, in workers' compensation cases, to be $74,000. Economic considerations due to direct and indirect health care costs, as well as patient quality of life issues, are therefore significant. Work disability due to CTS may be prolonged and, in fact, sufferers may need to change occupations even if treated surgically.

There is a bright side, though. The condition is usually controlled adequately with simple conservative measures. Nearly 90 percent of persons reporting mild symptoms are expected to recover completely

Table 1
Examples of Job Tasks and Occupations Associated with Carpal Tunnel Syndrome

Job Tasks	Occupation
handling child safety caps	pharmacist and technician
handling objects on conveyor belts	assembly line worker
hand weeding	gardener
using a spray gun	painter
playing a stringed instrument with bow	musician
using laser scanner	cashier
key punching, typing	computer operator

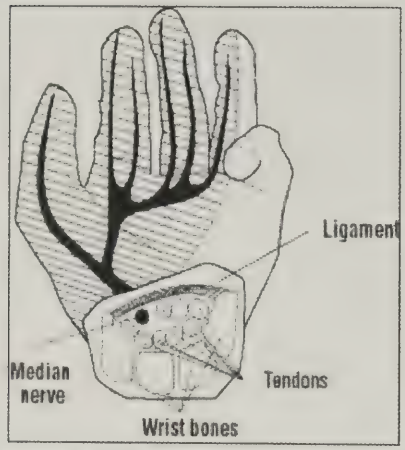

Figure 1. Left hand showing carpal tunnel and distribution of median nerve (shaded area).

with appropriate treatment. Sufferers can learn to reduce their chance for re-injury by changing the frequency and process of repetitive movements, and increasing rest periods between work sessions.

This lesson is the first in a two-part series that describes CTS and its management. In Part 1, discussion centers on describing factors known to aggravate the condition. It describes etiologic and pathogenic considerations, and identifies symptoms and clinical assessment procedures. Part 2 in the lesson series discusses management of CTS with medical and nonmedical interventions. It also provides information to help patients understand the disorder and obtain maximum benefit from treatment.

Anatomical and Physiological Considerations

Figure 1 shows anatomical features of the wrist that are relevant to an understanding of CTS. A canal (tunnel) extends along the longitudinal axis connecting the forearm with the hand. Within this canal are located the nine tendons that control finger movement, and the median nerve that innervates the thumb, index finger, middle (long) finger, and adjacent half of the fourth (ring) finger. The median nerve transmits impulses from the brain to the innervated fingers and hand, and transports information about temperature, touch, and pain from the hand to the brain. It is the only nerve within the carpal tunnel.

The carpal tunnel, named after the eight carpal bones of the wrist, is bound on the dorsal and lateral aspects by bone and a strong, broad ligament called the transverse carpal ligament on the volar surface. The carpal tunnel is a clearly limited space that cannot enlarge significantly. Any factor that alters its shape or competes for the limited space, such as changes following a fracture or with bending the wrist sharply, can exert sufficient pressure on the median nerve to compress or "pinch" it. This can result in distal motor and sensory dysfunction.

Tenosynovitis (i.e., inflammation of a tendon sheath) within the tunnel is the most common cause of symptoms. Inflammation can be caused by numerous factors including repetitive use of the hand and wrist. Symptoms often begin during pregnancy in response to fluid retention. Oral contraceptives may also incite fluid retention, as can numerous medical conditions, including thyroid disorders and connective tissue disease.

CTS is accurately described as a disorder affecting the median nerve at the wrist brought on by repetitive stress, physical injury, or other conditions that produce swelling of the tissues around the nerve. When inflamed, the tissues within the tunnel thicken and expand in size and, thereby, compress the median nerve. The outcome is pain, numbness, and tingling (paresthesias) in the wrist, hand, first three fingers and adjacent half of the fourth – the zone of distribution of the median nerve. The little finger and half of the ring finger adjacent to it are spared of symptoms since they are not innervated by the median nerve. Compression incites symptoms of discomfort in the radial-palmar aspect of the hand, palm, and wrist, and may also be perceived proximal to the compression site, even into the forearm and shoulder. Discomfort is usually more intense at night. Sensory deficit in the palmar aspect of the affected fingers and/or weakness with eventual atrophy of muscles controlling movement of the thumb can occur.

Pathophysiology

The tissue pressure within a compartment of the arm (i.e., the carpal tunnel) is normally 7-8 mm Hg. This pressure may increase in CTS to 30 mm Hg or more, near the point at which damage to the median nerve can occur. Pressure may increase to 90 mm Hg or higher with wrist flexion or extension. At these high levels, ischemia adds to the basic dilemma that leads to the syndrome. As sensory function is impaired over time, the individual may attempt to compensate by adopting a more forceful grip or developing other compensatory maneuvers that can intensify symptoms and add further injury.

The increased pressure within the canal is usually caused by nonspecific flexor tenosynovitis. Persons at high risk are typically between ages 40 and 60 years. Women are three times more likely than men to be affected. Table 2 identifies examples of disease processes associated with increased incidence of CTS.

Chronic focal compression of a nerve can deform its myelin sheath, the fatty substance that insulates nerve fibers. Approximately 1 percent of persons with CTS develop permanent injury. Ischemia accounts for the intermittent tingling that begins during the night or with wrist flexion. Ischemia may also contribute to irreparable damage to affected tissues.

Increasing grip force can increase carpal tunnel pressures and accelerate CTS. Fingertip force applied to tools and other objects being held is increased when there is diminished sensation, such as exposure to cold weather, or when wearing thick gloves or using vibrating tools.

Table 2
Examples of Diseases and Situations Associated with Carpal Tunnel Syndrome

Occupations (see Table 1)
Trauma
Osteoarthritis
Rheumatoid arthritis
Gout
Diabetes mellitus
Congestive heart disease
Edema
Obesity
Infection (e.g, Lyme disease, rubella, *Mycobacterium* sp.)
Amyloidosis
Hypo- or hyperthyroidism
Acromegaly
Median artery aneurysms
Congenital defects in carpal tunnel
Tumors of the tendon sheaths
Wrist fractures and dislocations
Ganglionic cysts
Lipomas
Thrombosed artery
Pregnancy
Use of oral contraceptives
Menopause
Gynecological surgery

A correlation between the ratio of wrist thickness to width and median nerve sensory latency has been noted. Some individuals may have a naturally smaller carpal tunnel volume and, therefore, be at increased risk for symptoms. This correlation has been suggested more often for persons with square wrists (thickness and width are about the same) than those with the more common rectangular wrists. Not all investigators agree on the clinical relevance of this association.

Specific Factors

Hormonal Changes. Alterations in fluid retention during pregnancy and hormonal fluctuations associated with menopause, as noted earlier, may predispose some women to develop CTS. Symptoms associated with pregnancy are typically bilateral. Symptoms are often noted during the third trimester, and usually resolve after delivery.

Gender. The reason why females are at higher risk for CTS than males is not known. Part may be due to the hand-intensive nature of numerous domestic chores, typing, and other work traditionally attributed to women. Hormonal changes may also play a significant role. The influence of gender is wide open to continued debate and investigation.

Genetics. There may be increased risk of CTS in persons who have a family history of the condition. Research continues in an attempt to identify abnormalities in specific genes that regulate myelin. Another potential familial relationship may be that some individuals are born with abnormalities of the carpal bones.

Repetitive Motion as a Cause of Carpal Tunnel Syndrome

It is believed that the tendons within the tunnel can become inflamed when people use their fingers intensively and/or bend their wrists repetitively over time. This results in localized injury with an inflammatory response that may lead to tendon and synovial disorders, muscle tears, ligamentous disorders, degenerative joint disease, bursitis, or nerve entrapment. Because the immovable borders of the tunnel do not provide for extra space to accommodate this swelling, the median nerve is compressed and symptoms appear.

At high risk for CTS are persons whose occupations demand repeated grasping, turning and/or twisting, or applying force to the fingers and hand for long periods. Stressful hand, arm, and neck positions from activities such as working long hours at a desk or driving long distances can aggravate the potential for damage. Persons at risk include those who use hand-held vibrating tools such as chain saws and jackhammers. They also include individuals in food processing industries, assembly line workers, musicians, postal workers, and dentists and dental technicians. Any worker who moves his hands and wrists repetitively is at some risk. Note that Table 1 includes a partial list of specific job tasks and occupations noted to have a high incidence of CTS among their workers. Repetitive stress injuries may also result from sports activities including rowing, golf, tennis, downhill skiing, archery, competitive shooting, and rock climbing.

Clinical Assessment

CTS may be difficult to diagnose definitively. About 25 percent of patients with work-related repetitive stress disorders will show false-positive evidence of other conditions whose symptoms resemble CTS. Moreover, it is often difficult to determine whether the primary cause is due to vocational or avocational (i.e., recreational pursuits, hobbies) conditions or an underlying pathology.

A positive diagnosis is suggested by the patient's vocational history and enhanced by the presence of one or more disorders known to aggravate symptoms. CTS is then confirmed upon presentation of appropriate symptoms (pain, tingling, etc. depicted in the pattern shown in Figure 1), physical findings (Phalen's maneuver, Tinel's sign, or decreased sensation to pin prick or vibration), and objective evidence via electromyogram or median nerve conduction defect at the wrist. Phalen's maneuver (wrist-flexion test) is performed by holding the forearms upright and bending the wrists 90 degrees. Individuals with CTS feel symptoms in the median nerve distribution within 60 seconds. Tinel's sign is positive when symptoms appear in the distribution of the median nerve while tapping over the nerve at the wrist. As expected, these physical tests have a high incidence of false positive results and, used alone, are often of doubtful clinical significance. In one study of 2,466 persons in a general population, 14 percent reported symptoms in the distribution of the median nerve. Nerve conduction studies confirmed median nerve neuropathy in approximately 45

Table 3
NIOSH Definition of Work-Related Carpal Tunnel Syndrome

Criteria A, B, and C must be met:

A. *Symptoms suggestive of CTS*
Tingling, pain or numbness affecting at least part of the median nerve distribution of the hand

B. *Objective findings consistent with CTS*
(1) One or more of the following physical findings: Tinel's sign, Phalen's maneuver, or decreased or absent sensation to pin prick in the median nerve distribution of the hand; or
(2) Electrodiagnostic findings of median nerve dysfunction across the carpal tunnel

C. *Evidence of work relatedness* (one or more of the following): frequent, repetitive or forceful hand work on affected side; sustained awkward hand position; use of vibrating tools; prolonged pressure over wrist or base of palm; temporal relationship of symptoms to work or association with carpal tunnel syndrome noted in co-workers.

percent of these symptomatic patients. It was interesting to note that nerve conduction studies were negative in nearly one-third of "clinically certain" patients and positive in approximately one-third of "clinically uncertain" patients. Of 125 asymptomatic patients in the control group, 18 percent were shown to have median nerve neuropathy on nerve conduction testing. Consensus committees representing the American Academy of Neurology, American Academy of Physical Medicine and Rehabilitation, and American Association of Electrodiagnostic Medicine now recognize nerve conduction studies as the diagnostic standard for CTS.

The National Institute for Occupational Safety and Health (NIOSH) has proposed a surveillance case definition for work-related CTS (Table 3). A positive diagnosis requires the presence of median nerve symptoms; one or more occupational risk factors; and objective evidence of CTS, including one of three physical examination findings or nerve conduction tests diagnostic of CTS.

Symptoms

Symptoms range from minor inconvenience to severe and disabling. Many mild cases resolve on their own following avoidance of aggravating factors. For example, following pregnancy as noted earlier, peripheral edema with swelling in the wrists disappears and symptoms of CTS abate.

Often, the patient's chief complaint is awakening at night with episodic bouts of tingling or numbness in one or both hands. Symptoms may also appear while driving or working at a keyboard. Symptom onset is often insidious, developing over months or longer. Numbness in the fingertips may be described as a "pins and needles" response, or as tingling. Individuals may say their "hand is asleep." As noted earlier, mild symptoms typically involve the first three digits and at times the radial half of the fourth finger. Mild symptoms are often relieved by hanging the hands down or "flicking" the wrists as if shaking down a thermometer. Over 70 percent of patients complain of nocturnal numbness of the hand; about 40 percent experience proximal forearm pain concurrent with tingling.

There is often a subjective feeling of uselessness or clumsiness of the fingers during activities requiring fine motor skills, such as buttoning a shirt or blouse, writing, sewing, unscrewing a bottle top, turning a key, or picking up small objects. Objects such as dishes or an article of clothing may be dropped. Patients may not be able to distinguish hot from cold. Their hands may feel swollen even though there is no visible inflammation. In severe cases, pain in the hand or wrist is usually described as aching or burning. It may feel like "electric shocks." The person may complain of shooting or darting pains from the center of the wrist or forearm into the hand, sometimes extending upward to the shoulder, neck, and chest. Sensory loss in the area innervated by the median nerve, weakness of these muscles, and slowing of nerve conduction across the carpal tunnel are characteristic.

Symptoms usually progress gradually over a period of weeks to months, and in some cases, years. Left untreated, severe cases may lead to atrophy of muscles at the base of the thumb with subsequent loss of sensation. Symptoms can be so crippling as to prohibit affected individuals from performing even simple tasks at home.

Summary

CTS is the most common cause of nocturnal hand discomfort and pain, and a frequent cause of work disability. It is also controlled in many patients by simple prophylactic and treatment measures. Affected individuals should learn how to avoid exerting undue stress on the hands and wrists, and perform regular exercises to strengthen the fingers, hands, wrists, forearms, shoulders, and neck. There is little evidence that any of these methods can provide complete protection against CTS, but all need to be explored early in therapy.

Continuing Education Quiz

This month's questions are taken from the article on "Carpal Tunnel Syndrome: Part 1: The Condition, Symptoms and Risk Factors". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 8/15/07. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-04-008-H01.

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Date Completed _____
(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. Carpal tunnel syndrome is a component of a group of pathologies that include all of the following EXCEPT:
   a. chronic upper limb pain syndrome.
   b. rheumatoid arthritis.
   c. nerve entrapment disorder.
   d. repetitive motion injury.

2. The percentage of persons with mild symptoms of carpal tunnel syndrome who are expected to recover completely with appropriate treatment is:
   a. 30.
   b. 50.
   c. 70.
   d. 90.

3. The number of tendons within the carpal tunnel that control finger movement is:
   a. one.
   b. three.
   c. nine.
   d. twelve.

4. Tenosynovitis describes inflammation of the:
   a. tendon sheath.
   b. median carpal nerve.
   c. tendons within the ring finger.
   d. transverse carpal ligament.

5. The outcome of pain, numbness and tingling associated with carpal tunnel syndrome is least likely to occur in the:
   a. little finger.
   b. ring finger.
   c. index finger.
   d. thumb.

6. Alterations in fluid retention during pregnancy are most likely to predispose women to develop carpal tunnel syndrome during the:
   a. first trimester.
   b. second trimester.
   c. third trimester.
   d. post-partum stage.

7. The gender at highest risk for developing carpal tunnel syndrome is:
   a. males.
   b. females.

8. The diagnostic test for carpal tunnel syndrome performed by holding the forearms upright and bending the wrists 90 degrees is called:
   a. Carpal's maneuver.
   b. Heimlich's maneuver.
   c. McBurney's maneuver.
   d. Phalen's maneuver.

9. Concensus committees representing three major national medical associations recognize which of the following as the diagnostic standard for carpal tunnel syndrome?
   a. CAT Scanning
   b. Electrographic testing
   c. Magnetic resonance imaging
   d. Nerve conduction studies

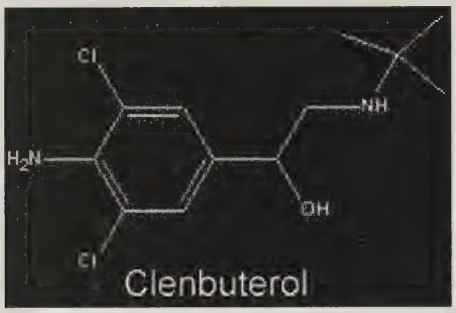
10. Approximately 70 percent of patients with carpal tunnel syndrome complain of nocturnal numbness of the:
   a. arm.
   b. elbow.
   c. hand.
   d. wrist.

Clenbuterol – Drug of Abuse

Author: Dawn Sobieraj, Pharm.D. Candidate 2005

In January 2005, the Maryland Poison Center received reports that contaminated heroin was being sold in New York, New Jersey and Pennsylvania. Initially, the contaminant was suspected to be cyanide. Analysis of samples of the "heroin" found clenbuterol, a bronchodilator as well as an illegal performance enhancing substance. A number of drug abusers who used the tainted product presented to New Jersey and New York hospitals with symptoms of agitation, nausea, severe headaches and weakness. Clinical effects also included hypotension and tachycardia; some patients experienced hypokalemia and acidemia. All patients survived.

Clenbuterol is a direct acting beta-2 agonist with a half-life of approximately 30 hours. Other drugs in this class include albuterol and salmeterol.



In 1998 the Food and Drug Administration (FDA) approved this medication as a new animal drug application under the brand name Ventipulmin® Syrup. Its use is restricted to the treatment of horses with obstructive airway disease such as chronic obstructive pulmonary disease (COPD). It is not approved for use in any animals that are intended for human consumption. Use in humans is illegal in the United States, however it is manufactured for human use in foreign countries.

In addition to its bronchodilating properties, clenbuterol also has effects that can be compared to those of anabolic steroids. When taken orally, clenbuterol has a strong anti-catabolic effect. This reduces the rate at which protein is metabolized in the muscle cell, resulting in an enlargement of muscle fibers. In addition, clenbuterol has been shown to be a thermogenic compound. It increases body temperature slightly, requiring a greater number of calories to be burned to fuel this process, resulting in a fat-burning effect. Many athletes and body builders take clenbuterol after using anabolic steroids. As a result, they develop the maximum amount of strength and muscle mass while burning the greatest amount of body fat.

Male athletes typically take 100-140 mcg per day, while female athletes require approximately 80-100 mcg/day. Since clenbuterol is not a hormone it does not result in the same side effects characteristic of anabolic steroids. Common side effects of clenbuterol include restlessness, nausea, tachycardia, palpitations, tremor, headache, increased perspiration, insomnia, muscle spasms and hypertension. These side effects usually subside after 8-10 days of continued use. Hyperglycemia and metabolic acidosis have been reported with other medications that have sympathomimetic activity comparable to clenbuterol, therefore these adverse effects may be a concern.

Since 1988 clenbuterol has also been used illegally in livestock to build up muscle mass and decrease fat in animals that are raised for slaughter and human consumption. A small amount added to an animal's feed has the potential to increase the animal's lean meat by up to 15% while reducing its fat content by 30%. If the animal is treated with clenbuterol up until the day of slaughter, the animal has approximately 40 times the legal limit of clenbuterol in its lean muscle. This poses a serious risk to humans that consume the meat. Unfortunately, clenbuterol residues remain in the tissues for a long period of time, especially the liver, kidneys and retinal fluid; therefore, there is still a risk to consumers, even if the drug is discontinued days to weeks before slaughter.

In 1990 there were 135 cases of people that became critically ill in Spain after consuming beef liver contaminated with clenbuterol residues. The victims had symptoms that included tachycardia, muscle tremors, headache, dizziness, nausea, fever and chills. The same year there were reports of 22 hospitalizations in France for the same symptoms following ingestion of meat products. Throughout the rest of Europe, thousands more beef and pork consumers have suffered similar symptoms, all of which can be linked to the sympathomimetic clenbuterol. There has been at least one death

attributed to clenbuterol residues contained in contaminated meat.

If a patient has been exposed to clenbuterol, they should be monitored for changes in vital signs, electrocardiograms (EKGs), blood glucose and electrolytes. Treatment of clenbuterol toxicity includes supplemental oxygen, benzodiazepines such as diazepam or lorazepam to counter the central nervous system (CNS) stimulant effects, a short acting beta-blocker such as esmolol for symptomatic tachycardia and vasopressors such as dopamine or norepinephrine to treat hypotension. Due to clenbuterol's 30-hour half-life, the patient may require observation and treatment for an extended period of time.

The long-term effects of clenbuterol are also a cause for concern. The drug is known to accumulate in the liver, which may cause serious hepatotoxicity over an extended period of exposure. Also, patients that take beta-blockers such as propranolol are at risk for therapeutic failure due to the beta-2 agonism of clenbuterol.

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Special Thanks to Wendy Klein-Schwartz, Pharm.D., M.P.H., University of Maryland School of Pharmacy, for reviewing this article.

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LAWBOOK—In order to provide you with the legal information you need to practice pharmacy in Maryland, the Maryland Pharmacists Association (MPhA), Judge John Fader (ret.), and the Law Book Committee have collaborated to restructure and update the current publication entitled Pharmacy Laws and Regulations for the State of Maryland. The XII Edition is now available. To order by credit card call the MPhA Office.

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Dedication
Richard D. Baylis, CGP, FASCP

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"An Update for Pharmacists"

Continuing Education
"Carpal Tunnel Syndrome: Part II: Medical and Non-Medical Interventions"

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President

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Maryland Pharmacists Association

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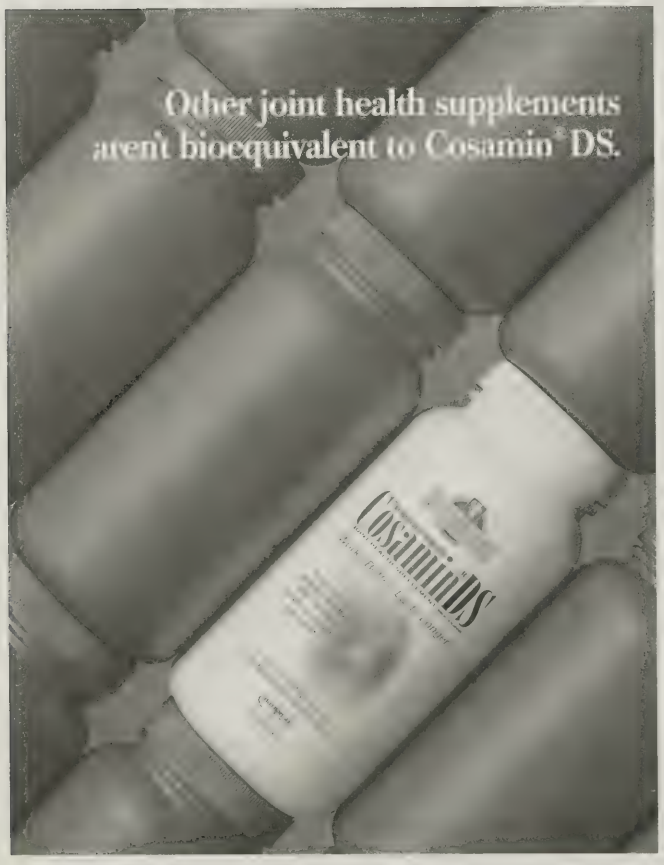

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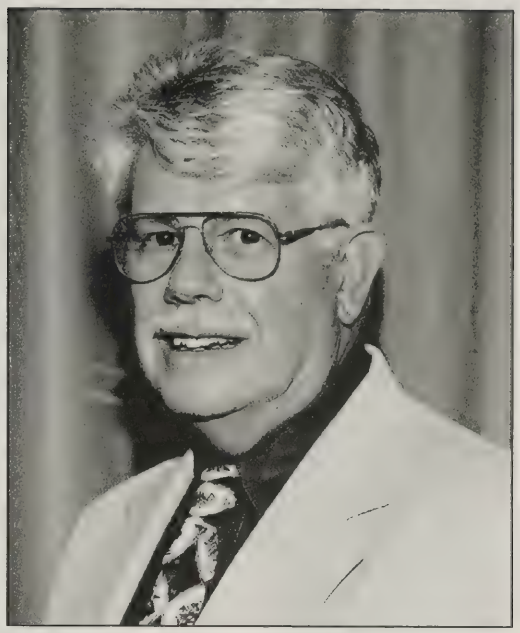

Richard D. Baylis, CGP, FASCP

Richard,

It is truly hard to believe that you have "really" retired! I speak for MPhA in wishing you well on your move to Georgia and that houseboat (by the way you did promise the use of your new home for meetings or even a future Midyear). We at the association will always appreciate your tireless work on so many facets of the organization, but mostly the work that will continue on the Kelly building and its museums. The job is not done but it will forever be a tribute to your commitment to Maryland Pharmacy.

Good Luck!

Matthew Shimoda, Pharm.D.

President, MPhA

Richard Baylis who has had a long and distinguished career in Maryland pharmacy is about to retire. It is hard to imagine Maryland pharmacy without Dick's involvement. Dick's hard work and tireless efforts have helped to raise the bar on pharmacy practice, public policy debates and pharmacy history in Maryland. A graduate of Albany College of Pharmacy in New York, Dick has worked in community, hospital and LTC pharmacy over the past 44 years. Since 1980, he has worked for Howard and Morris Institutional Service—an Omnicare Company—and has created a unique and innovative consultant pharmacist practice at Levindale. He has been actively engaged as a preceptor in the position of Associate Professor for both the University of Maryland School of Pharmacy and Howard University, teaching multiple pharmacy students every year in his special practice setting. He has also served from 1990 to 1996 as the Drug Utilization Review Director for the Maryland Pharmacists Association. In 1996, Dick became a Board Certified Consultant Pharmacist in the State of New Jersey and in 1997 became one of the first group of practitioners to become a Certified Geriatric Pharmacist (CGP) under the new program of CCGP. He has made numerous presentations over the years and has had articles published in the *Maryland Pharmacist* and *The Consultant Pharmacist.*

Dick has worked with the Maryland Board of Pharmacy on committees such as the Task Force on Collaborative Practice and has been extremely active in pharmacy's professional organizations. Since 1961, Dick has served in many capacities with the Maryland Pharmacists Association (MPhA) including Trustee, Co-Chair Legislative Committee, Chair Building Committee, Vice-President, President, and Chairman of the Board. He was a driving force behind the renovations to the Kelly Building in Baltimore and a major contributor to re-opening the B. Olive Cole Pharmacy Museum. Dick worked hard providing much of the physical labor of cleaning glassware in the museum, setting up shelving, hauling trash and hanging signs. He received the Seidman Distinguished Achievement Award in 2005, MPhA's highest award for pharmacy service.

Dick has also served as Chairman of the Maryland Pharmacy Coalition and was very active in its formation and activities. Dick has been an active member of ASCP since 1990. Nationally he has been a part of the Government Affairs Committee, the Political Action Committee and the Nominating Committee. He has been extremely involved with the Maryland Chapter since its reorganization in 1995, serving as President, Board member and Chair of the Mid-Atlantic Conference Planning Committee for many years. Dick's hard work has helped to build the Mid-Atlantic Conference into the exceptional meeting it is today. In 2001, Dick was recognized by the Maryland Chapter of ASCP with the "Pharmacist of the Year Award." At the August 2005 Mid-Atlantic Conference in Cambridge, Maryland, Dick was awarded the Maryland ASCP Lifetime Achievement Award for his many years of dedicated service.

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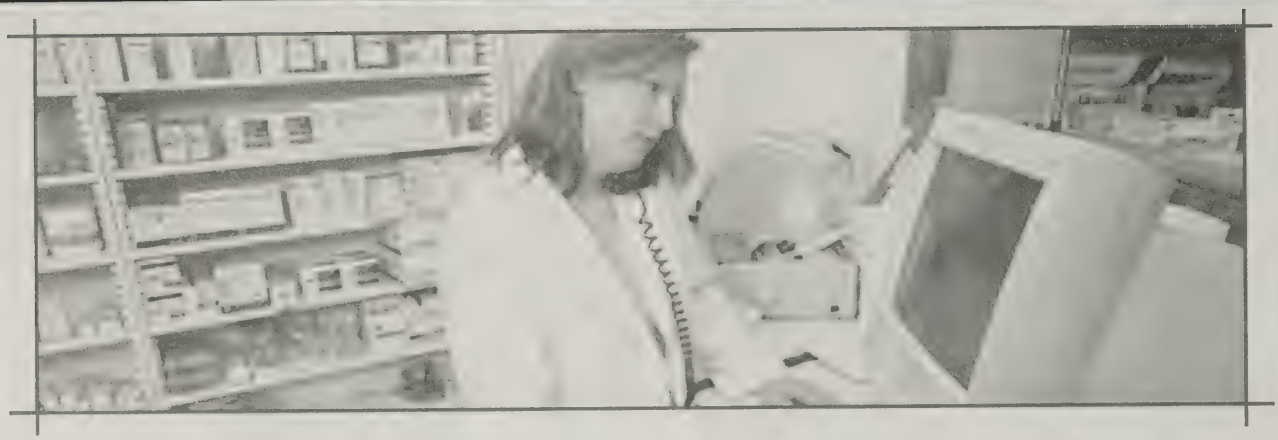

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Maryland Pharmacists Association Constitution and Bylaws

The House of Delegates approved recommended changes to the Constitution and Bylaws at the June 13, 2005 meeting in Ocean City, MD. In accordance with the revision process, an affirmative vote of at least a two- thirds majority of members responding to this mailing is required for these amendments to become part of the Constitution and Bylaws. Following is a reprint of only those sections with recommendations for substantive changes. Recommended changes are consistent with strategic planning initiatives and other pertinent factors affecting Association business objectives. For further details regarding rationale of recommended revisions or for a full copy of the Constitution and Bylaws, please contact the Association Headquarters.

Constitution

Article II. Mission

~~The mission of MPhA is to serve members, to represent Pharmacists, and to promote the highest standards of professional practice in Maryland.~~The mission of MPhA is to promote excellence in pharmacy practice, strengthen the profession of pharmacy, and advocate for all Maryland Pharmacists.

Article III. Purpose

~~To promote the advancement of the profession of pharmacy.~~

~~To promote the common interest of those engaged in or associated with the practice of Pharmacy in the State of Maryland.~~

~~To promote and safeguard the public health and welfare of the people of the State of Maryland.~~

~~To promote the proper use of drugs, medicines and health care devices.~~

~~To promote cooperation with other health care professionals and organizations~~

~~To promote the professional and economic interests of pharmacists.~~

The purpose of MPhA is to promote:

- The health and well-being of Maryland citizens.
- Safe and effective use of medications and health care devices.
- Collaboration among health care professionals and organizations.
- Professional competence.
- Leadership development.
- Responsible legislation and regulation.
- The history and tradition of Maryland Pharmacy.

Article VI. Officers

The Officers of the MPhA shall be active members of the Association and consist of the President, ~~First Vice-President~~ Vice President (who shall be the President-elect), ~~Second Vice-President,~~ Treasurer, and the Immediate Past President (who shall serve as Chairman of the Board of Trustees).

Bylaws

Article II. Board of Trustees

A. Composition

The Board of Trustees shall be composed of ~~nineteen (19)~~thirteen (13) members which shall include the following Officers: Immediate Past President, who shall serve as Chairman; President; ~~First Vice-President~~ Vice President, who shall be the President-elect~~, Second Vice-President~~; Treasurer; Speaker of the House of Delegates; ~~and~~ Vice Speaker of the House of Delegates, who shall be the Speaker-elect; ~~eleven (11)~~six(6) elected Trustees; and one(1) Trustee who is ~~a member~~the President or designee of the Academy of Students ~~of Pharmacy~~Pharmacists of the University of Maryland School of Pharmacy. Ex-officio members of the Board of Trustees shall include the Executive Director of the Maryland Pharmacists Association, the Dean of the University of Maryland School of Pharmacy, and the President or designee from each of the following organizations: ~~Chairman of the Board of~~ the Maryland Society of Health System Pharmacists, ~~the President of~~ the Maryland Chapter of the American Society of Consultant Pharmacists, and the Maryland Pharmaceutical Society ~~and the Dean of the University of Maryland School of Pharmacy~~. No ex-officio member shall have voting privileges.

B. Terms of Office

Elected Trustees ~~will~~ shall serve for staggered three (3) year terms, ~~four~~ two (2) elected each year~~, except every third year when the number elected shall be three~~. Any Trustee shall be eligible for reelection up to a maximum of three (3) consecutive terms. A vote by the Association members to elect the~~Election of~~ Trustees shall be ~~by mail ballot~~initiated within sixty (60) days after nominations have been certified by the House of Delegates. The results of the election shall be reported to the Board of Trustees by a Canvassing Committee appointed by the President. Newly elected Trustees, upon installation, immediately enter upon the performance of their duties and shall continue in office until their successors are elected and installed, or unless they resign, are removed, or are otherwise unable to fulfill an unexpired term.

Article III. Officers

A. Terms of Office and Elections

The President ~~and First Vice President~~ shall be a non-elected positions. The ~~Second Vice President and Treasurer~~ Vice President (who will be the President-elect) shall be elected annually and the Treasurer shall be elected biannually by ~~mail ballot~~a vote of the Association members initiated within sixty (60) days after nominations have been ~~certified~~ approved by the House of Delegates. The results shall be reported to the Board of Trustees by a Canvassing Committee appointed by the President.

F. Treasurer

The Treasurer shall ~~keep~~ ensure the maintenance of an account of all monies received, invested, and expended ~~for the use of~~ by the Association; shall oversee disbursements authorized by the Board of Trustees; and shall make a report at the Annual Meeting or when called upon by the President. All sums received shall be deposited in institutions approved by the Board of Trustees. Funds may be drawn only upon the signature of the Treasurer and one ~~or more~~ of the individuals approved by the Board of Trustees. The funds, books, and vouchers and the Treasurer's control shall be at all times subject to the verification and inspection by the Board of Trustees. The Treasurer shall ensure that an audit of the books by an accounting firm approved by the Board of Trustees be performed on an annual basis and also upon a significant change of Association staff. The Treasurer shall ensure that all required tax returns and other governmental requirements be performed in a timely manner. The Treasurer shall chair the Budget and Finance Committee, which is responsible for drafting an annual budget to present to the Board of Trustees.

Article VI. House of Delegates

C. Officers of the House of Delegates

The Officers of the House of Delegates shall consist of the Speaker, Vice Speaker (who shall be the Speaker-elect), and the Secretary. The Executive Director of the Maryland Pharmacists Association shall serve as Secretary but shall not be entitled to a vote.

F. Duties of the Vice Speaker of the House

The Vice Speaker shall be the Speaker-elect, and~~The Vice-Speaker shall~~ preside at meetings of the House of Delegates when the Speaker is unavailable,~~.~~ and ~~The Vice-Speaker shall serve as Chairman of the Resolutions Committee. The Vice-Speaker will~~ assume the duties of the Speaker in the event that the Speaker cannot fulfill the duties of that office. The Vice Speaker shall serve as chair of the Resolutions Committee. The term of office for the Vice Speaker is one year. Upon completion of his/her term of office, the Vice Speaker shall automatically assume the office of Speaker of the House.

J. Resolutions Committee

Resolutions may be submitted to the Resolutions Committee any time prior to the last meeting of the Committee which precedes the Annual Meeting. In addition, resolutions bearing the signature of two active members may be presented to the Speaker or the Secretary of the House of Delegates at least 24 hours prior to consideration by the House.

The Resolutions Committee shall be appointed by the Speaker of the House of Delegates at least ~~forty-five (45)~~ninety (90) days prior to the ~~annual meeting~~Annual Meeting of the Association. ~~The Resolutions Committee shall be chaired by the Vice-Speaker of the House of Delegates.~~ In the absence or incapacity of the Vice Speaker, a member appointed by the Speaker of the House shall serve as ~~Chairman~~chair of the Resolutions Committee.

The Resolutions Committee ~~will~~ shall submit all resolutions to the Board of Trustees at the meeting scheduled in the month prior to the Annual Meeting.~~for review at a regularly scheduled meeting of the Board prior to presentation to the House of Delegates.~~ The Board of Trustees shall review each

resolution and make a recommendation that the House of Delegates~~take a position on each resolution. The House of Delegates may~~ adopt, defeat, or refer ~~any resolution~~ to a committee.

K. Election of the Speaker and Vice Speaker of the House

The House Nominating Committee shall be responsible for the nomination of candidates for the office of~~s of Speaker and~~ Vice Speaker of the House of Delegates. The office of Speaker of the House of Delegates is automatically filled by the current Vice Speaker. In the event that the Vice Speaker is unable to serve as Speaker, the House Nominating Committee shall be responsible for nomination of candidates for the office of Speaker of the House of Delegates.

The House Nominating Committee will present a slate of at least two candidates (if possible) for each position to a session of the House of Delegates at the Annual Meeting. The House Nominating Committee shall consider experience and demonstrated leadership abilities. Members of the House Nominating Committee may not be nominated for any position.

If approved by the House, an election ~~will~~ shall be held at the final session of the House of Delegates at which time the new Officers of the House of Delegates ~~will~~ shall be installed.

Article VII. Committees

B. Nominating Committee

The Vice President shall serve as chair of the Nominating Committee. The Nominating Committee shall ~~At least three (3) months prior to a meeting of the House of Delegates, the President, subject to the approval of the Board of Trustees, shall appoint a Nominating Committee of at least four (4) members in good standing to~~ nominate at least two (2) individuals (if possible) for each forthcoming available seat on the Board of Trustees and ~~each~~ the office ~~except First~~ of Vice President, and Treasurer (on alternate years)~~President and Chairman of the Board~~. The Nominating Committee shall consider geographic diversity, ~~and~~ practice specialty, and experience in making its nominations. Nominees for the offices of Vice President and Treasurer shall have a minimum of 2 years MPhA Board of Trustees experience. ~~The First Vice-President shall serve as chair of the Nominating Committee.~~ The slate of candidates shall be presented to the House of Delegates at the Mid-Year meeting. Members of the Nominating Committee may not be nominated for any position.

C. Budget and Finance Committee

The Treasurer shall serve as ~~T~~the chair of the Budget and Finance Committee. ~~shall consist of the Treasurer as Chairman, the Chairman of the Board of Trustees, the President, the First Vice-President, and up to two (2) additional members in good standing.~~ A proposed annual budget of the Association ~~will~~ shall be prepared by the Budget and Finance Committee and presented to the Board of Trustees for its approval at least two (2) months prior to the beginning of the fiscal year.

~~***D. Audit Committee***~~

~~The President, First Vice-President and two (2) additional members in good standing who do not serve on the Finance and Budget Committee shall comprise an Audit Committee. On a semi-annual basis, the Audit Committee shall review the accounts, financial transactions, and general economic status of the Association and report its findings to the Board of Trustees.~~

D. Past Presidents' Council

The Past Presidents' Council shall be comprised of all~~the ten (10) immediate~~ past presidents who are current members. ~~not currently serving on the Board of Trustees.~~ The Past Presidents' Council shall be responsible for the selection of the Honorary President as well as the recipients of all MPhA ~~scholarships and~~ awards. Selection shall be by a majority vote of at least a minimum of 50% of the Past Presidents responding within 30 days to a notice for a meeting of the Past Presidents' Council. The President~~Board of Trustees~~ may designate additional responsibilities to the Past Presidents' Council as directed by the Board of Trustees. The Past Presidents' Council shall be chaired by the most recent~~immediate past Chairman of~~ past president not currently serving on the Board of Trustees.

Fold

Constitution and Bylaws
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650 W. Lombard Street
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The recommended changes to the Constitution and Bylaws

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Rx AND THE LAW

By Karen E. Peterson, R.Ph., J.D.

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PHARMACISTS' DUTY TO WARN: NO CLEAR ANSWERS

Imagine the following scenario: When presented with a prescription, you fill it after thorough and appropriate DUR. Then you counsel the patient. Despite your best efforts, the patient experiences an adverse event related to the medication. She sues you, alleging that you failed to properly warn her about the risks associated with the medication. Is it possible you could be found liable? In an increasing number of jurisdictions, the answer to that question is "Yes." However, as the following recent examples illustrate, there still exists confusion over the issue of whether pharmacists have a duty to warn.

On March 3, 2005, the Court of Appeals in Georgia affirmed the trial court's finding that the pharmacist did not have a duty to warn the plaintiff of every potential side effect of a medication.[1] In this case, the plaintiff presented a prescription for Daypro to the pharmacy.[2] The pharmacist filled the prescription properly. The plaintiff testified that although she had been experiencing headaches, dry and itchy eyes, and flu-like symptoms for several days prior to having the prescription filled, she did not ask to speak to the pharmacist when she picked up the prescription because she had no questions or concerns. The pharmacist, although he had no specific recollection of this patient, testified that it was his habit to counsel all patients.[3]

The day after the Daypro prescription was filled, the plaintiff developed blisters in her mouth and had difficulty breathing. She presented to the emergency room and was diagnosed with Stevens-Johnson syndrome, a rare, extreme allergic reaction to medication. The plaintiff sued Kmart on the theory that failure to warn of potential side effects of Daypro, including Stevens-Johnson syndrome, was a violation of the standard of care for pharmacists.

The court examined the Board of Pharmacy rules on counseling and found that those rules "do not establish a duty to warn about every possible side effect of a drug."[4] This finding was due in part to the testimony of plaintiff's own physician expert. He testified that, due to the rarity of Stevens-Johnson syndrome, he did not warn his own patients about that potential reaction when he prescribed Daypro. The court's finding had the effect of upholding the learned intermediary doctrine in Georgia, with the

[1] Chamblin, et al v. Kmart Corp., 612 S.E.2d 25 (2005).

[2] She had begun using samples of Daypro approximately 14 days before having the prescription filled.

[3] The plaintiff offered no evidence to show that an offer to counsel was *not* made.

[4] Chamblin, *supra* at 27; Ga. Comp. R. & Regs. R. 480-31-.01(c)(1).

reasoning that "the treating physician is in a better position to warn a patient of the dangers associated with a drug."[5] However, the court did not go so far as to say a pharmacist's only duty was to fill prescriptions correctly as they are written. The court left open the possibility that a different set of facts may change its stance on the issue of a pharmacist's duty to warn.

That is precisely what happened in Florida. In this case, the husband of a woman who died as a result of an overdose of oxycodone and diazepam sued the prescriber, as well as two pharmacies that filled the prescriptions.[6] The physician had written and the pharmacies had filled multiple controlled substances prescriptions for the patient over a period of about six months. The plaintiff alleged "that the pharmacies owed [the decedent] a duty to provide for the health, safety and welfare of its customers who had their prescriptions filled there commensurate with the prevailing professional standard of care."[7] The pharmacies argued that the claims should be dismissed because "Florida does not allow a negligence claim against a pharmacy for properly filling a lawful prescription."[8]

The court reviewed the statute that describes the duties of a pharmacist in dispensing medication[9] and determined that pharmacists are "already specifically charged with general knowledge of prescription medication and the risks presented by taking particular prescription drugs."[10] As such, the Fourth District Court of Appeals found that "a strong policy basis already exists supporting a pharmacist's duty to warn customers of the risks inherent in filling repeated and unreasonable prescriptions with potentially fatal consequences," and subsequently reversed the trial court's dismissal of the plaintiff's claims against the pharmacies. [11]

The court acknowledged that its holding is in conflict with holdings in two other Florida districts where, when presented with similar facts, the court found that the pharmacist had no duty to warn.[12] In addition, the court noted that simply because the plaintiff's claims against the pharmacies survived the motion to dismiss did not mean the plaintiff would prevail at trial or in a summary judgment motion.

The only clear trend among the opinions seems to be that, given the right set of facts, courts appear willing to impose a duty to warn on pharmacists. What is a practicing pharmacist to do when faced with conflicting opinions on the issue of a pharmacist's duty to warn? Certainly it is important to be aware of the law on this issue in your jurisdiction. However, the use of sound professional judgment in counseling patients is the best way to protect your patients and yourself. Do not wait for a court to tell you how to care for your patients.

©Karen E. Peterson is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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[5] Chamblin, *supra* at 27.
[6] Powers v. Thobani, et al, 2005 WL 1278930.
[7] Powers, *id* at 1.
[8] *Id.*
[9] Fla. Stat. § 465.003(6)
[10] Powers, *supra* at 3.
[11] *Id.*
[12] Johnson v. Walgreen Co., 675 So. 2d 1036 (Fla. 1st DCA 1996) and Estate of Sharp v. Omnicare, Inc., 879 So. 2d 34 (Fla. 5th DCA 2004)

Medicare Part D: An Update for Pharmacists

Author: Nicole J. Brandt, PharmD, CGP, BCPP
Co-Author: Cherokee Layson-Wolf, Pharm.D., CGP

Background

Increasingly, pharmacists are seeing older Americans struggling with the cost of medications with patients compromising between which prescriptions to fill and how much. The increasing number of prescriptions, more frequent higher-priced medication prescribed, and rising cost of the medications are factors that contribute to the growing prescription drug expenditure. It is estimated that one-third of Medicare beneficiaries do not have medication coverage, an estimated 20% more have coverage for only part of the year, and are forced to pay out of pocket for part or all of their prescription cost. This accounts for a 44% rise in total prescription spending by senior citizens from 2000 to 2003. [1] *In 2000, 34% of all prescriptions were dispensed to elderly, which accounts for 42 cents of every dollar that is spent on prescriptions.* [2] *With these facts in mind the necessity of a health care system that provides prescription drug coverage for today's society becomes evident. This is why it is essential for pharmacists in all aspects of healthcare to be aware of the impact of the Medicare Prescription Drug Improvement and Modernization Act of 2003.*

What is the Timeline?

Many of you have more than likely seen the Medicare Discount cards that were introduced in 2004. Individuals that truly benefited from the program were those whose income was less than 135 percent of the poverty level and who were not eligible for other prescription assistance programs. They qualified for a $600 credit each year totaling $1,200 depending on when they enrolled and the enrollment fee was waived. This program is an intermediary for the Medicare prescription plan which will start in January 2006.

Currently, the Social Security Administration is sending out applications to assess one's means and see if they are eligible for additional assistance. Individuals who have Medicaid essentially the "dually eligible" will not receive this. However, numerous other older Americans are receiving these applications which can lead to questions to pharmacists on why they should fill out this application. As advocates for the individual, pharmacists should advise and assist these individuals because it may lead to additional assistance with medication cost and potentially better prescription coverage. Contracts for prescription drug plans (PDP's) and other Medicare health plans (MA-PD's), have been submitted to the Centers of Medicare and Medicaid Services (CMS). Plan information will not be available until after contracts are signed in September and marketing will begin in October 2005. Individuals will be able to be enrolled starting November 15– December 21, 2005 and their coverage will begin January 1, 2006. If an individual joins January 1–May 15, 2006, coverage begins the month after they join. It is advised that individuals join when first eligible in order to pay the lowest monthly premium. It is estimated that the monthly premium will be approximately $37 a month in 2006.

What will the Medicare Prescription Drug Plan offer?

Medicare Prescription Drug Plans must offer standard drug benefit and may also offer supplemental or enhanced benefits. Plans must provide information about service areas, benefits, cost sharing, formulary, pharmacy access and other aspects of coverage available through the plan.

What most Medicare Prescription Drug Plan enrollee will be responsible for:
(www.cms.hhs.gov/medicarereform/newcovprescdrug.pdf):

- Generally less than $37 monthly premium
- $250 deductible
- Coinsurance of 25% of drug costs from $250 to $2,250, Medicare pays 75%
- 100% of drug costs from $2,250 to $5,100
- After $3,600 in out-of-pocket costs, Medicare pays approximately 95%

In addition to the prescription drug benefit offered by Medicare Part D, the MMA also includes stipulations for the coverage of Medication Therapy Management services. These services, which includes comprehensive medication review and making appropriate drug therapy recommendations, will be provided at no cost to the beneficiary and pharmacists may be compensated for these services provided in their practice settings. While the provision of these services are not limited to pharmacists, pharmacists are mentioned as the primary provider of these services. This provides a unique opportunity to obtain compensation for cognitive services.

What is meant by True Out of Pocket (TrOOP) spending?
This is the $3,600 to reach catastrophic coverage which consists of:

1. Deductible—$250 in 2006
2. 25% coinsurance—$500 in 2006
3. 100% between $2,250 and $5,100—$2,850 in 2006.

It is important to note that the Medicare prescription drug plan premium is not part of out-of-pocket threshold.
In addition, payments for employee/retiree group health plans, TRICARE, Black Lung, Veterans Affairs, worker's compensation, automobile/no-fault/liability insurance, supplemental benefit portions of PDP or MA-PD, most third party payment arrangements, drugs purchased outside the US, over-the-counter drugs, drugs not on the Plan's formulary and drugs not covered by law (Table 1) do NOT go towards TrOOP. An example under standard benefit of how this works:

1. Met $250 deductible
2. Gets a prescription for $100
3. PDP pays $75
4. Person with Medicare pays $25
5. $250 deductible and $25 coinsurance are counted toward out-of-pocket threshold

This is going to be an online adjudication and tracking system to give beneficiaries updates of their status. At this time, it is not yet known what the plans formularies will consist of. CMS will ensure formularies do not discourage enrollment among certain groups of people. Formulary review requirements are posted on the (www.cms.hhs.gov/pdps) website.

Who is eligible and how do they enroll?
Any individual who is entitled to Medicare Part A and/or enrolled in Part B. This means not only older individuals, but also those who are disabled. Enrollment in this plan is voluntary and does not occur automatically like other Medicare benefits. The potential beneficiary must choose a plan available in the area in which they reside. Individuals eligible for Medicare prescription drug coverage may enroll in a Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug plan (MA-PD plan). People enrolled in an MA plan must receive Medicare prescription drug coverage from the MA-PD plan.

If someone needs help choosing a plan:

- Visit www.medicare.gov and get personalized information
- Call 1-800-MEDICARE, TTY users should call 1-877-486-2048
- Call the local SHIP (available through the local office on aging)

What are the enrollment periods?
In general, the enrollment periods for PDP's and MA-PD's are similar. The consist of three enrollment periods:

1. Initial Enrollment Period (IEP)
    - November 15, 2005, through May 15, 2006, for people who:
        - are currently eligible or
        - will become eligible in November, December 2005, and January 2006
    - For everyone else, the Initial Enrollment Period is similar to the Initial Enrollment Period for Part B (a 7-month enrollment period):
        - three months before eligibility for Medicare prescription drug coverage
        - the month of eligibility and
        - months after eligibility for Medicare prescription drug coverage
2. Annual Coordinated Election Period (AEP)
    - For the first year, the AEP is the same as the Initial Enrollment Period (November 15, 2005, through May 15, 2006)
    - In 2006 and after, the AEP is from (November 15 through December 31 of each year)
3. Special Enrollment Period (SEP)
    - Permanent move out of the plan service area
    - Individual entering, residing in, or leaving a long-term care facility
    - Involuntary loss, reduction, or non-notification of creditable coverage
    - Other exceptional circumstances. In general, a person with Medicare may unenroll from a PDP only during the annual coordinated election period, or a special enrollment period.

What is YOUR ROLE?

The role of the pharmacist is not just education but also advocacy. There are numerous resources available and the CMS partnership information on the web (www.cms.hhs.gov/ partnerships/tools/tools/materials/ medicaretraining/MPDCoutreachkit.asp) will send out a FREE outreach toolkit. (Table 2) Many beneficiaries will want to know which plan is best for them based upon the medications they are taking. Pharmacists as well as other providers should not steer beneficiaries into plans that are based upon the financial self-interest of the provider rather the best interest of the beneficiary. CMS has developed guidance on permitted marketing information and regulations. (www.cms.hhs.gov/pdps/PrtDPlnMarktngGdlns.asp) Over the next several months you will see a great deal of activity and programs surrounding the Part D benefit.

It is essential for all pharmacists in all practice settings to learn as much as possible in order to not only educate themselves but other healthcare professionals and prospective beneficiaries and their caregivers. This will help to maximize the positive aspects while minimizing the challenges of the Medicare Prescription Plan. In addition, this is a critical time for pharmacists to become providers for the medication therapy management programs which will consist of interventions targeting beneficiaries with chronic diseases, on multiple medications or with high annual medications costs (> $4,000). Pharmacists are experts in medication management and will be essential to the implementation of Medicare Prescription Plan. It is time we set our personal perspectives aside and advocate for the betterment of our patients and their families and friends—because they will truly need us NOW!

Table 1: Medications that are Excluded

Medications	Exceptions
Anorexia, weight loss, or weight gain agents	
Fertility medications	
Medications for Cosmetic purposes or hair growth	
Symptomatic relief of cough and colds	
Prescription vitamins and mineral products	Prenatal vitamins and fluoride preparations
Non-prescription drugs	
Barbiturates	There is a growing concern among providers regarding access to these medications and many states such as Maryland are working on providing coverage for some of these excluded medications.
Benzodiazepines	

Table 2: Additional Resources

Medicare: www.medicare.gov • Publications such as: *Medicare & You* handbook and *Facts About Medicare Prescription Drug Plans* • 1-800-MEDICARE
Centers for Medicare and Medicaid Services: www.cms.hhs.gov • Pharmacists resource page: http://www.cms.hhs.gov/medicarereform/pharmacy/ • Order the Outreach Toolkit: http://www.cms.hhs.gov/partnerships/tools/materials/medicaretraining/ MPDCoutreachkit.asp
Social Security Administration: www.socialsecurity.gov or 1-800-772-1213
American Pharmacists Association: www.aphanet.org
National Association of Chain Drug Stores: www.nacds.org
National Community Pharmacists Association: www.ncpanet.org • Medicare Resource Center: http://www.medicareresourcecenter.com/

Reference:
(1) Families USA. Out-of-Bounds: Rising Prescription Drug Prices for Seniors. http://www.familiesusa.org/site/DocServer/Out_of_Bounds.pdf?docID=1522 (Accessed 2004 Nov 20)

(2) Families USA. Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010. http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726 (Accessed 2004 Nov 20)

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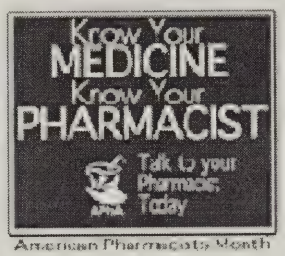

October 2005

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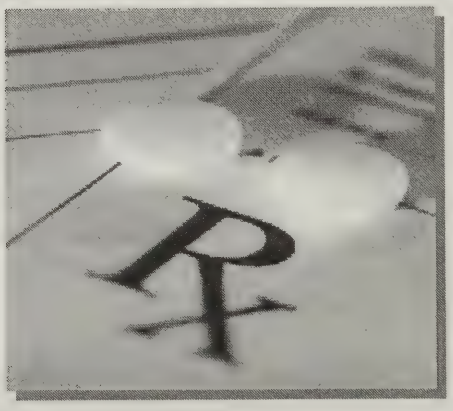

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Continuing Education for Pharmacists

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Carpal Tunnel Syndrome: Part 2: Medical and Nonmedical Interventions

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this two-part lesson series are to discuss carpal tunnel syndrome and provide information on its management with medical and nonmedical interventions.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify drugs employed in therapy of carpal tunnel syndrome and discuss their rationale and use;
2. choose nonmedical interventions to manage carpal tunnel syndrome and describe their rationale and use; and
3. select specific information for patients that will enhance their understanding of the disorder and help them obtain maximum benefit from their therapy.

This is the second in a two-part lesson series that describes carpal tunnel syndrome (CTS) and its

Gossel

Wuest

management. In this lesson, discussion centers on the medical and nonmedical interventions in management of CTS. It also provides information for patients to help them understand their condition and maximize response to treatment. Part 1 in this series discussed etiologic and pathogenic considerations, and identified symptoms and clinical assessment.

Carpal Tunnel Syndrome in Review

CTS is described as a disorder affecting the median nerve at the wrist brought on by repetitive stress, physical injury, or other conditions that produce swelling of the tissues around the nerve. When inflamed, tendons and/or other tissues within the tunnel thicken and expand in size, thereby compressing the median nerve. The outcome is pain, numbness, and/or paresthesia (tingling) in the wrist, hand, first three fingers and adjacent half of the fourth finger – the zone of distribution of the median nerve. The little finger and half of the ring finger adjacent to it are spared of symptoms since they are not innervated by the median nerve. Compression incites symptoms of discomfort in the radial-palmar aspect of the hand, palm, and wrist, and may also be perceived proximal to the compression site, even into the forearm and shoulder. Discomfort is usually more intense at night. Sensory deficit in the palmar aspect of the affected fingers and/or weakness with eventual atrophy of muscles controlling movement of the thumb can occur. It is believed that 3 percent of adults in the U.S. are affected. Individuals in high-risk vocations and avocations (recreational pursuits, hobbies) are at greater risk.

Management

Treatment options in CTS have remained essentially unchanged over the years. Noninvasive (i.e., conservative) measures are commonly the first choice, and reported to be effective in approximately 90 percent of patients. Early management requires consideration of the relationship between symptoms and occupational or recreational activities and their modification as appropriate. Mainstays in the nonsurgical management of CTS include minimizing flexion of the wrist, wearing a support to maintain the wrist in a neutral (e.g., aligned) position, and using anti-inflammatory medication. This protocol is especially beneficial in patients with acute flare-ups and those with mild and intermittent symptoms.

It is important to begin managing the early phases of CTS before neural damage progresses. Affected individuals should avoid activities that may aggravate symptoms. This encourages inflamed tissues to return to normal size and, therefore, relieve pressure on the median nerve. Conservative management

Score 1 point for each "yes" answer and zero for each "no" answer.*

Have symptoms been present for more than 10 months?
Yes___ No___

Does the patient have constant tingling? **Yes___ No___**

Does the patient have flexor tenosynovitis (pain from flexing the fingers)? **Yes___ No___**

Is Phalen's Maneuver positive within less than 30 seconds?
Yes___ No___

Is the patient older than 50 years?
Yes___ No___

Scoring Key: zero points = 65 percent success rate; 1 point = 41.4 percent success rate; 2 points = 16.7 percent success rate; 3 points = 6.8 percent success rate; 4 or 5 points = 0 percent success rate.

*Outcome rates are based on the use of wrist splinting and NSAIDs; success rates may be higher with oral corticosteroid therapy or local corticosteroid injection.

From: Kaplan SJ, Glickel SZ, Eaton RG. *J Hand Surg.* 1990;15:106

Figure 1. Instrument to help predict the outcome of conservative treatment for carpal tunnel syndrome.

works best in men under 40 years of age, and less well in women. Any technique to relieve pressure on the nerve and promote circulation in the microvascular blood supply is likely to lessen symptoms.

Oral Medications. The most commonly used drugs include nonsteroidal anti-inflammatory drugs (NSAIDs) and these form the backbone of drug therapy. Diuretics, oral corticosteroids, and pyridoxine (vitamin B_6) are used less often and with various degrees of success. NSAIDs may help reduce swelling and, therefore, pain in mild to moderate cases. The lowest effective doses should be employed initially, with increasing dosages only if necessary.

Orally administered corticosteroids have been shown in some clinical trials to be more effective than NSAIDs or diuretics in short-term therapy of CTS. In one prospective, randomized, double-blind, placebo-controlled trial enrolling 73 patients, global symptoms scores for CTS were improved significantly at two weeks and four weeks in patients receiving prednisolone 20 mg/day for two weeks, followed by 10 mg/day for two weeks. No major adverse effects were noted. The optimal corticosteroid dosage remains unknown.

It is known that pyridoxine deficiency can cause peripheral neuropathy and that a pyridoxine deficiency has been identified in some patients with CTS. This has led to use of the vitamin in an attempt to attenuate symptoms. Most experts agree that, in the absence of deficiency, oral administration of pyridoxine is of questionable value. Nonetheless, some patients may benefit from increasing their dietary intake of the vitamin. Rich sources include brewer's yeast, soybeans, walnuts, lentils, brown rice, and bananas. The recommended dietary allowance (RDA) for vitamin B_6 is 2 mg for males over age 15, and 1.6 mg for females over age 15.

If symptoms subside with conservative management techniques, the individual may progress to a supervised program of physical therapy. This includes exercises to strengthen the hands and improve body posture, which will be further explained. If symptoms continue to be bothersome, an injectable corticosteroid may be employed. One group of investigators has designed an instrument to help predict the outcome of conservative treatment based on risk factors. This is shown in Figure 1.

Local Injections. Corticosteroids alone or combined with a local anesthetic may be injected into or proximal to the carpal tunnel to provide relief of mild to moderate symptoms when other, more conservative, measures have not provided sufficient relief of symptoms. Steroid injections into the tunnel may confer initial relief, but relapses are common, and chemical or mechanical nerve injury can occur.

A randomized, double-blind trial enrolling 60 patients with confirmed CTS compared oral corticosteroid therapy and local corticosteroid injection. Thirty patients received a local injection of methylprednisolone 15 mg, plus oral placebo. The other 30 patients received orally administered prednisolone 15 mg for 10 days plus a saline injection. Mean global symptoms scores for both groups did not differ significantly at two weeks. However, at eight and 12 weeks, improvement was enhanced significantly in the methylprednisolone injection group.

Ergonomics. Coined from the Greek stems *ergos*, meaning work, and *nomos*, meaning laws, the term *ergonomics* has become a buzzword to describe a broad variety of conditions, appliances, and objects associated with specific tasks in the work environment. The term is sometimes used synonymously with human factors. Practically speaking, ergonomics relates to the interface between individuals and their environment. Ergonomics is the study and control of posture, stresses, motions, equipment, procedures, and other physical forces on the human body. The overall goal with ergonomics is that people can optimize their vocational and recreational performance without impediment from these forces.

For example, altering the way a person performs repetitive activities may help prevent inflammation in the hand and wrist and, therefore, keep their condition from progressing into full-blown CTS. Good posture is especially important for keyboard users. This includes sitting straight with the spine against the back of the chair, keeping shoulders relaxed and elbows held along the side of the body or supported on chair arms,

and holding the wrists aligned with the forearms. Feet should be placed firmly on the floor or on a footrest. Books and pages being typed from should be held at eye level so that the neck is not bent over the work. This keeps the neck flexible and head upright to maintain circulation and nerve function to the arms and hands.

Tension on the keys should be adjusted if possible so that depressing them does not cause fatigue. The hands and wrists should remain in a relaxed position to avoid excessive force. Using an ergonomically correct keyboard will be beneficial in many cases since the arms will be held in a more natural position. Cushion supports at the front edge of the keyboard can help keep the wrists and fingers in a comfortable position.

Tools and utensils should be shaped appropriately and held so that the position of the wrist is in proper alignment with the hands. Their handles should be designed so that the force required to hold them is distributed across the muscle between the base of the thumb and the little finger. Those designed for use by persons with arthritis usually work well for persons with CTS. They typically have handles with large diameters. Using tools and utensils with textured handles is often helpful because they may be felt easily, requiring a less intensive grip. When holding objects such as a pen or pencil, steering wheel, bicycle handlebars, or tools for prolonged periods, the individual should grip them as loosely as possible. Working at low temperatures that reduce sensation in hands and fingers, and with tools and machines that vibrate excessively, such as chain saws, electric sanders, and jackhammers, should be avoided.

Exercise. A structured exercise regimen that combines aerobic with resistance motion can strengthen muscles in the hands, wrists, arms, shoulders, and back. This will also help in weight loss and improve overall health, well-being, and posture. People who are physically fit are at lower risk for repetitive stress disorders. Persons should first check with their physician about an appropriate regimen if they have not been exercising regularly.

Supports and Braces. The importance of maintaining the wrist at a neutral angle to reduce the incidence and intensity of symptoms cannot be overemphasized. This can be achieved with use of elastic wrist supports and braces that hold the wrist straight, especially during work and sleep. During the early stages of CTS, a simple elastic support will oftentimes control symptoms, especially nighttime numbness and pain. As the condition progresses, wrist support will aid in medication control of symptoms and help keep doses at low levels. An occasional report will speak negatively against use of wrist supports in that they may aggravate the condition by reducing circulation and restricting movement. If such problem exists, the device was most likely not fitted properly. In fact, any device that restricts movement and promotes good hand posture will relieve stress on the tendons, reduce inflammation, and reduce or eliminate CTS symptoms. The correct use of wrist supports and braces will be discussed in more detail in the sections that follow.

Ultrasound Therapy. Ultrasound therapy may be beneficial in the long-term management of CTS. In a double-blind, randomized, clinical investigation that compared ultrasound treatment with "sham ultrasound" treatment (i.e., control), 20 sessions of ultrasound therapy to the carpal tunnel administered over seven weeks resulted in significantly greater improvement of symptoms at two weeks, seven weeks, and six months. Additional studies are needed to confirm the usefulness of ultrasound therapy since other studies have shown no benefit for this procedure.

Surgery. In severe cases or when supports and braces, oral anti-inflammatory agents and/or corticosteroid injections into or proximal to the carpal tunnel, and other conservative medical treatments fail to alleviate symptoms, surgery may be necessary. The procedure consists of releasing the tension of the ligament that forms a tight roof over the tunnel to relieve pressure on the median nerve. The outpatient procedure is reported to be one of the most successful surgeries performed on the hand. A survey of 400 U.S. hand surgeons revealed an average of 65 surgeries per physician annually. Two-thirds of patients who experienced carpal tunnel

Table 1
Advice for Wrist Supports and Braces

- A variety of wrist supports and braces are available and intended for various uses.
- This product may be worn anytime during the day or night.
- If your condition persists or worsens, discontinue use of this product and consult your doctor for advice.
- Follow the instructions included with this product for proper product care and use.
- To select the correct size of a wrist support or brace, measure around the smallest part of your wrist. Compare this measurement with the chart on the package. Sizes are the same for men and women. If you cannot find your correct size, ask your pharmacist for assistance.
- A wrist support or brace should be snug enough to help hold your wrist in proper position, but not so tight as to occlude blood flow into your hand. If your hand feels cold or you feel throbbing or other symptoms that are different from the symptoms you are treating with the support, discontinue use of the product and talk to your pharmacist or doctor.
- Some wrist products contain natural rubber latex that may cause allergic reactions. If you develop a rash, itching, or other discomfort underneath the product or on your skin nearby, stop using the product and talk to your pharmacist or doctor.

Table 2
Advice for Patients with Carpal Tunnel Syndrome (CTS)

- CTS is not limited to office workers or factory assembly-line workers. Many, if not most, patients with the disorder have never done this type of work.
- Your doctor or pharmacist may recommend a support to keep your wrist and hand in proper alignment. The support will be especially beneficial if worn during sleep.
- If you have a job that requires repetitive motion with your hands, make sure your wrists and arms have adequate support.
- Alternate tasks, if possible, to reduce the amount of repetitive movements.
- A number of sports and recreational activities can worsen carpal tunnel symptoms. If you have any questions about these, talk to your doctor or pharmacist.
- Modify or change your daily activities (including work and hobbies) that put pressure on your wrists.
- Avoid injury to your wrists or hands by wearing protective equipment when appropriate (e.g., when roller skating).
- If you have diabetes, try to keep your blood sugar under control.
- Use hand tools of the appropriate width, size, and shape – that is, make sure that you can grip the tool comfortably, that the tool can absorb vibration, and that the handles are positioned to keep your wrists and hands in alignment.
- If you are obese, try to lose weight.
- If you smoke, try to quit.
- Ergonomically designed furniture may help reduce symptoms. Modify your work environment if possible. A healthy computer workstation includes an adjustable keyboard table and chair, and a wrist rest.
- Shaking or rubbing your hands while holding them upward often brings relief from symptoms.
- If symptoms have been present for a short time, or have been caused by a brief flurry of activity, over-the-counter anti-inflammatory medications may be all that is needed. Talk to your doctor or pharmacist about this.

release in one report indicated complete or near-complete satisfaction with the outcome at six, 18, and 30 months after surgery.

Emphasis on Wrist Supports

In treating CTS, it is important that the wrist be maintained in alignment with the forearm as closely as possible. A properly fitted wrist support or brace may be all that is needed for effective relief from symptoms in the absence of identifiable serious pathology. This is especially important during periods of stress associated with work, hobbies, or sporting events, and when other conditions are present to cause the wrist to bend sharply. Supporting the wrist during sleep when symptoms may become sufficiently intense to awaken the person repeatedly and prohibit restful sleep is particularly important.

Fitting Wrist Supports and Braces. Wrist supports and braces must be fitted carefully and correctly. Many types are available from a host of suppliers. Custom-fit products can also be ordered from specialty medical goods distributors. The Internet lists dozens of suppliers of products and many are suitable and safe to use. At the same time, purchasers may have little or no assurance they will receive a product that is fitted correctly or can be returned without undue hassle if it is unsuitable. Therefore, the advice and counsel of a trained health care professional concurrent with the sale in a local pharmacy, for example, will be invaluable. Manufacturers of ready-to-wear supports and braces provide detailed sizing charts on the package. They can also provide other resources to pharmacists on fitting these appliances.

Information for Patients

Pharmacists may be the first health care professional with whom patients will discuss their symptoms. There are several items of importance to consider when discussing CTS. Certain individuals should not wear wrist supports without first consulting a physician for advice. Those who suffer from severe occlusive arterial disorders such as Raynaud's disease, and others with dermatologic infection or topical allergies to latex rubber in the products should not use them without their physician's approval. In the first instance, the appliances may decrease arterial blood supply into the tissues of the hand, which may increase symptom severity or onset of other pathology. In the second example, the products may incite an allergic response. Patients with these conditions should first consult their physician about the products.

Recommending an appropriate support or brace begins by ensuring that patients understand the relationship between the factors that aggravate symptoms and the importance of trying to avoid them. At this point, a brace that will accomplish the patient's goals may be selected. Information of value to patients with CTS is summarized in Tables 1 and 2.

Continuing Education Quiz

This month's questions are taken from the article on "Carpal Tunnel Syndrome: Part 2: Medical and Nonmedical Interventions". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 9/15/07. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-04-009-H01.

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(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. Carpal tunnel syndrome (CTS) is a disorder affecting which of the following nerves in the wrist?
   a. Collateral
   b. Median
   c. Sciatic
   d. Vagus

2. The onset of carpal tunnel syndrome includes paresthesia which refers to which of the following sensations?
   a. Itching
   b. Spasm
   c. Tingling
   d. Weakness

3. Mainstays in the nonsurgical management of carpal tunnel syndrome include all of the following EXCEPT:
   a. minimizing flexion of the wrist.
   b. wearing a wrist support.
   c. using an anti-inflammatory medication.
   d. repetitive weight-bearing exercises.

4. A deficiency of which of the following vitamins is most likely to cause peripheral neuropathy?
   a. Pyridoxine
   b. Niacin
   c. Thiamine
   d. Riboflavin

5. Ergonomics is a study of all of the following EXCEPT:
   a. body posture.
   b. external stresses.
   c. cost of therapy.
   d. equipment use.

6. Good posture important for keyboard users includes all of the following EXCEPT:
   a. sitting straight with the spine against the back of the chair.
   b. keeping the shoulders relaxed with elbows along the side of the body.
   c. holding the wrists aligned with the forearms.
   d. placing what is being typed below and to the left of the keyboard.

7. A properly fitted elastic wrist support will hold the wrist:
   a. straight.
   b. bent upward.
   c. sideways.
   d. bent downward.

8. To select the correct size of a wrist support, the measurement should be taken around the:
   a. largest part of the wrist.
   b. smallest part of the wrist.

9. All of the following are true regarding CTS EXCEPT:
   a. Most CTS patients are office and factory assembly-line workers.
   b. wrist supports are especially beneficial when worn during sleep.
   c. patients with CTS should alternate tasks, if possible, to reduce the amount of repetitive movements.
   d. shaking or rubbing hands while holding them upward often brings relief from CTS symptoms.

10. Patients with which of the following conditions should not wear a wrist support without first consulting a physician for fear of increasing symptom severity?
   a. Congestive heart failure
   b. Occlusive arterial disorders
   c. Osteoarthritis
   d. Osteoporosis

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MARYLAND Pharmacist

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Medicare Prescription Plan Part D

Katrina
Volunteers

Membership
Investment Form

Continuing Education
"Management of Erectile Dysfunction: Focus on Levitra & Cialis"

HAPPY HOLIDAYS!!!

MARYLAND PHARMACISTS ASSOCIATION

OCT./NOV./DEC. 2005

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OUTCOMES

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Important Information
CareFirst BCBS Medicare Prescription Drug Plan MTM Program

CareFirst BCBS has announced it will utilize community pharmacists as the providers of MTM services in its Medicare Prescription Drug Plan (Medi-CareFirst). Outcomes Pharmaceutical Health Care will administer the MTM program.

Covered Services
Beginning January 1st, 2006, all Medi-CareFirst members will be eligible for a full menu of face-to-face MTM services. The covered services, and the corresponding professional fees, appear below:

- Comprehensive Medication Reviews (CMR) $30.00
- Physician Consultations $20.00
- Patient Compliance Consultations $20.00
- Patient Education & Monitoring $10.00

Becoming a Provider
To be eligible to provide these MTM services and receive professional fees, pharmacists must complete the Outcomes Personal Pharmacist Training program. Training may be completed in three ways:

LIVE TRAINING:
- See the Upcoming Live Training Opportunities document for more details.

ONLINE TRAINING: $20 (single-user; ACPE credit available)
- Go to www.getoutcomes.com
- Under Quick Links, select "Pharmacist Training Program"

TRAINING CD-ROM: $10 (multi-user; ACPE credit not available)
- Go to www.getoutcomes.com
- Under Quick Links, select "Order Supplies"
- Under "Multimedia," select "Personal Pharmacist Training CD-ROM"

Pharmacy Contracting
To participate in the CareFirst MTM program, each pharmacy must complete a Participating Pharmacy Agreement.
- Go to www.getoutcomes.com
- Under Quick Links, select "Participating Pharmacy Agreement"

MTM Directory
CareFirst BCBS will create a directory of MTM-participating pharmacies for its members to access. **The initial MTM directory will include only those pharmacies in the CareFirst dispensing network that have completed a Participating Pharmacy Agreement and that have pharmacists who have completed Personal Pharmacist Training by November 30th, 2005.**

601 E Locust Suite 200 Des Moines IA 50309-1946
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Seasons Greetings!

I hope this holiday season finds you and your families well. I know that as I look forward to this time of joy and good cheer I have a "little friend" sitting on my shoulder whispering strange things into my ear. Medicare Part D, Region 5, MTM, PDL's, Dual Eligible and other acronyms that go on and on. It has been a process taking over 2 years and is the most sweeping piece of legislation to hit Pharmacy in the last half century. I look back to the Medicare Modernization Act of 2003 and think I knew it was going to be big but, what the heck it was somewhere off in the future and "if" it really did come about I had time to get ready. Well it is here and boy has it consumed the Pharmacy profession like nothing we have seen (almost makes the HIPPA regulations look like a drug company CE at Ruth Chris Steak House).

The approximately 42 million Americans eligible for Medicare Part D come to us confused and looking for our help. We as professionals look to this with mixed feelings. We are at times just as confused or frustrated with the situation; and by the way we still need to help the other 200 million plus patients. Pharmacy is at the busiest time of the year with cough and cold season upon us, Avian Flu questions coming from consumers as well as other Health Care Professionals, "rumor control" about why our patients can't always get their Influenza vaccines, and just trying to keep our sanity as we juggle our professional and personal lives.

I hope I didn't get started on a gloomy note when we are trying to find that "joy" during this holiday season, because despite all of the above I find that as a pharmacist this has been a breath of fresh air. People are seeing the value of our profession. We have become the "go to" person when questions arise from 82 year old Mrs. Smith about her options and why her medication management has become more important, we are quoted in the news about how we "think" the programs will work, other Health Care Providers ask us our help, and on and on.

The profession of Pharmacy has a great opportunity to build upon this and be seen and used as the true professionals that we are. Part of me wants to take my vacation for the month of January, but deep down I look into the eyes of those patients asking questions and trust that I will help answer their questions and give them help just as I have done in the past. We at MPhA represent the profession of pharmacy and I am proud to say that our organization has been very proactive and a conduit, with not just the Medicare Part D but, many other timely issues. As I say this I ask for your help with MPhA. We have many committees dealing with all facets of pharmacy. As an individual these tasks look to be monumental, but with your help the individual becomes a group and the task not so monumental. Please consider helping with one of the many committees that are the backbone of our association and profession.

I am looking forward to seeing everyone at the Mid-Year meeting in Columbia on January 29, 2006 where the dialogue will continue.

Matthew Shimoda, Pharm.D.

Katrina

By Melvin Rubin

If we routinely practiced Pharmacy in Maryland the way we did in Louisiana during the immediate aftermath of Katrina, our licenses would be in jeopardy.

I was among a group of Pharmacist volunteers who were deployed to the Gulf Coast including Pei-sah Upshaw, Pat Louthan, Nneka Ezekwueche, Christine Musser, Rachel Strand, Timothy Lubin, Kassa Mesfin, Christopher Falato, Crystal Henderson, Debra Mcnutt, Matt Durkin, Joseph Loetell, and Steve Lauer. The first three and myself began Sept 5th, others followed. Working side by side with doctors, nurses and military personnel, we displayed just what Pharmacists can do in emergency situations.

Our workdays were typically 14-15 hours, and with only one Pharmacy open in the entire community we not only provided emergency medication and helped with the gamut of medical treatment, but worked with the National Guard and Red Cross to provide bottled water, food, consoling and hope. There were no businesses open and many homes were either uninhabitable or had suffered severe damage. Most telephone lines were down and some roads were still impassable. We resided in hospital rooms with 3-4 people per room. For the first week or so there was no air conditioning, no hot water, only bottled water for drinking and no food except for MRE's (meals ready to eat). The elevators did not work, so we carried supplies and equipment up and down three flights of stairs. Much of our time, initially, was spent on housekeeping chores such as mopping floor, clearing debris and trash, and disinfecting the areas to be worked in. By the end of my two weeks, some conditions were improving, especially the food, and 3 more Pharmacies had opened.

Delivering Pharmacy services under extreme conditions and with a limited supply of medication proved challenging. We had to make decisions on whether or not to fill a prescription with no remaining refills without being able to contact the original Pharmacy or the Physician and at times had to even determine what the patient used from only the information they could provide orally. When "Operation Lifeline" opened six clinics, we inventoried the medicine we had on hand and made determinations of what could be substituted to tide a patient over until a new prescription, written by a Maryland volunteer doctor, could be filled when more parish (county) pharmacies opened. We scrounged for medicine in every available corner: Doctor's office samples, medications never sent or returned in an abandoned hospital, and digging through FEMA shipments.

A commanding officer told the four Pharmacists who had been there longest, to take a day or evening off. We all disobeyed the order. We had been working with and being helped by the city residents who had lost a lot, if not everything and we had no choice but to get as much medicine sorted for the next day as possible. The real heroes are the people from the area who worked up to 20-hour days providing us with meals, some of the transportation and manpower at the clinics. We came home and they are still there. Some of these people were in tears accepting our help, crying both about the horrible events they had endured and the joy of having even the limited help we could give them. A few actually had smiles on their faces as they thanked us for our help.

God Bless them!

Rx AND THE LAW

By Rachel Jackson
and Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

MINORS AND PRESCRIPTIONS: WHERE DOES HIPAA FIT IN?

(Part 1 of 2)

Kate is the chief pharmacist for Hometown Pharmacy. Naturally, she fills and counsels prescriptions for the young and old, all day long. One day, Mrs. Johnson calls, asking if her 16-year-old daughter Jenny had recently gotten a prescription filled. Kate is suddenly faced with a very difficult issue: does she answer Mrs. Johnson, as she is the minor's caregiver? Or does she protect Jenny, replying that the information is confidential? Is a minor protected by HIPAA? What does the law say about the confidentiality of a minor's "protected" health information?

State and other applicable laws present three situations when dealing with prescriptions (or any health information) for a minor:

1) When the health care provider must treat the personal representative as the primary decision maker
2) When the health care provider must treat the minor individual as the primary decision maker (the personal representative does not have an absolute right to the information)
3) When the health care provider may treat either the minor or the personal representative as the primary decision maker.

In the first situation, a parent is usually the personal representative. Exceptions exist when the state law does not require consent from the parent for certain health services, when the court authorizes someone else to make treatment decisions, when a parent agrees to a confidential relationship between the minor and health care provider, or when abuse or endangerment is in question.

Pharmacists deal with the personal representative all the time: dispensing amoxicillin suspension for an 18-month-old, teaching the administration of ciprofloxacin eye drops for an 11-year-old, or recommending a dose of Pepto-Bismol for an 8-year-old. HIPAA isn't even called into question. When Hometown Pharmacy first dispenses a medication to baby Mark, Mark's mom or dad signs the Notice of Privacy, acting as the patient's personal representative.

The third situation is also very common as the minor grows older. Many state pharmacy laws say the 'patient or patient's caregiver' should receive counseling. However, there may be no distinction in pharmacy law as to when a pharmacist should deal with one over the other. When does a minor patient not require a caregiver anymore? Most state laws define a "minor" as an individual younger than 18, but 4 states differ. It's a good idea to check your own state laws on this.

Hometown Pharmacy may counsel 14-year-old Mike on his new acne medication, or may counsel Mike's mom if she's picking it up. It may be more difficult when trying to monitor for adverse effects. If Mike's minocycline causes him to have diarrhea, he may be embarrassed and not report it to his mother. If Kate consults Mike's mother, she would find no problems with

the medication and let it continue; if she talks to Mike, he may be more likely to complain since she can consult his doctor about changing the medication. There is no law specifically stating that you *can't* speak with a minor, and that you *must* speak with the personal representative.

The second situation is the trickiest, as laws vary from state to state. When is a minor the treatment decision maker? Read part 2 of the series to examine just how far HIPAA goes to protect a minor's confidential information, and how Kate at Hometown Pharmacy should handle the phone call with Mrs. Johnson.

For more information, see:

Boonstra H and Nash E. Minors and the right to consent to health care, *The Guttmacher Report on Public Policy*, 2000, 3(4):4–8. http://www.guttmacher.org/pubs/tgr/03/4/gr030404.pdf.

HIPAA Regulations. http://aspe.hhs.gov/admnsimp/pl104191.htm.

OCR Guidance Explaining Significant Aspects of the Privacy Rule – 4 Dec 2002. http://www.hhs.gov/ocr/hipaa/guidelines/personalrepresentatives.pdf.

Rebecca Gudeman. Adolescent Confidentiality and Privacy Under the Health Insurance Portability and Accountability Act. *Youth Law News: Journal of the National Center of Youth Law*. Jul-Sept 2003. http://www.youthlaw.org/downloads/adolescnt_confidentiality.pdf.

The American Bar Association. Facts about Children and the Law. 28 Dec 2000. http://www.abanet.org/media/factbooks/childlaw.pdf.

The Guttmacher Institute. Minors' Access to STD Services. Minors' Access to Contraceptive Services. *State Policies in Brief*. 1 Sept 2005. http://www.guttmacher.org/statecenter/spibs.

©Rachel Jackson and Karen Peterson. Rachel Jackson is a student at the Iowa College of Pharmacy in Iowa City, Iowa. Karen E. Peterson, R.Ph., J.D. is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Each year since 1992 the pharmacy school has sent a cadre of students to Salt Lake City Utah to participate in the Summer School on Alcoholism and Other Chemical Dependencies. Those selected spend a week immersed in a powerful learning experience and often come away changed in a fundamental way as regards their perception of addiction and especially of addicted pharmacists. This is one student's account provided with his permission and knowledge.

My "Utah Experience"

Joe Lewis, Pharm.D. 2006

At the University of Utah School on Alcoholism and Other Drug Dependencies (the Utah School), I learned a great deal about addiction and dependency within the pharmacy profession, while at the same time, I learned much about myself. Prior to attending the school, I expected an event where I may meet some people, but mostly, I expected to just stick with the people I arrived with and go to the lectures where people would talk *to* us. In actuality, my experience was far from that. It turned out that the majority of the attendants were recovering pharmacists who look forward to this school just as much as some children look forward to Christmas! Some actually place equal, if not more, importance on the certificate they receive at the end of the week than their pharmacy license! They welcomed me with open arms and wished me well with my "Utah Experience."

The Sunday after we arrived in Salt Lake City was Father's Day, which is a bittersweet day for me. The day began with my thoughts geared toward my dad, who took his life a little over five years ago after battling alcohol, crystal meth, and the demons in his own head. Some of us decided to see the Mormon Tabernacle Choir perform. They had a special Father's Day service, which turned out to be an emotional experience for me, since they obviously spoke a bit about fathers. The entire service transcended religious boundaries, and by the end of it, there was no doubt in my mind that I was right where I was supposed to be this week: at a program focusing on drug and alcohol abuse within my chosen profession.

The week did not only consist of lectures, which turned out to be extremely informative, lively, and at times, shocking, but also witnessed an actual counseling session with patients from a local recovery house. We did some hiking and touring of Salt Lake City, but also participated in Alcoholics Anonymous (AA), Narcotics Anonymous (NA) and Al-Anon meetings in the evening. It was at these meetings where things came out that could not be explained at a lecture. The participants who were recovering pharmacists shared their stories. We listened to their struggles, hardships, and personal triumphs. Through listening to them, my commitment to the profession of pharmacy was re-affirmed. I also felt my own father smiling down on me for getting involved in this positive experience. He himself had achieved sobriety when I was eight years old and attended AA meetings regularly. Unfortunately, as mentioned earlier, he had relapsed roughly ten years after he first got sober and committed the ultimate act of desperation. For this reason, I realized that if these recovering pharmacists, who at one point thought that they were so knowledgeable about medications that they would not abuse them, had a problem with narcotics and/or alcohol, I too could also face this dilemma (i.e. I too am not impervious to the realm of addiction). I realized that I needed to be vigilant and mindful of myself, especially given my family history and that I can very easily become that "kid in a candy store." Actually, that is the primary reason I got involved in SPA and SCODAE in the first place. These organizations seemed a perfect fit for me and my life experiences.

The warmth and openness of the attendants at this school made this week a truly memorable experience, which I will never forget. The lectures covered topics such as the pharmacology of addiction, ethics, pain management in the

addict, and chemical dependency in health professionals. I gained a much better understanding of addiction and my role as a future pharmacist with regard to how I should deal with somebody who might have a problem with drugs and/or alcohol from a professional standpoint. Again, it must be reiterated however that this was not truly the primary focus of the Utah School.

Everything we did over the week revolved around the themes of open-mindedness, compassion, willingness, commitment, and fellowship via the 12-step meetings. At the start of the Utah School on Sunday evening, every section met for a kick-off meeting presented by the school's director. He immediately set the tone for the week by welcoming all of us and reminding us all to keep an open mind and to, once again, enjoy the "experience". At our pharmacy section's first meeting, all of the new "students" were given a mentor to whom we could turn with any questions or comments. It was not anything formal, in which we were given assignments to hand into our mentors, but rather a primer for the week ahead. My mentor began our small group meeting by telling us a little about himself. He was a recovering pharmacist who was ecstatic to be in Utah for the week and had been looking forward to it for a long time. We then said a little about ourselves, and I shared how I was truly grateful to be able to take part in this week and how I could sense that my father was looking down upon me. Again, the sense of fellowship could not be denied. My mentor turned out to be a source of support throughout the week. He often checked in with me to see if I had any questions about any of the presentations; moreover, he came up to me after I shared at the Al-Anon meeting about my dad to thank me for my talk, adding that he knew I would speak up at some point during the meeting.

The Utah School concluded with another presentation by the school's director who spoke on the topic of family and friends. He asked us each to take a moment to mentally thank our loved ones for the sacrifices they may have made, allowing us to spend an entire week away from home. He also wanted us to meditate on events and topics throughout the week that were of significance to us and to come up with how we will ensure that those items will be put to use upon our return home. It was a wonderful way of reaffirming our commitment to the week's teachings as well as to our profession. I returned home with a sense of gratitude for being given the opportunity to participate in the Utah School as well as a forward momentum which I am sure will assist me in putting what I gained over the week to use as a student and a pharmacist in the future.

As already alluded to, the information presented benefited me personally, and I am confident that this will be reflected in organizations I am involved in on campus. The numerous contacts I made during the week may lead to a possible forum speaker or to perhaps something bigger, such as a collaborative effort between our organization and another one. Even if this is not the case, I have a list of people I can turn to in the future if I have a question or concern regarding alcohol and/or drug abuse. One thing is for sure: the "Utah Experience" proved my early expectations of the school to be completely false. It was an amazing experience, one which words cannot truly describe. I highly recommend the school to anyone who wants to get a better sense of addiction and various resources that exist to deal with it.

Kawasaki Disease

Nareesa Hassan, Pharm.D. Candidate 2006

When on one of my rotations as a 4th year student pharmacist, at the Children's National Medical Center in Washington, D.C., I heard about a few cases of Kawasaki Disease. In my previous coursework, I had never come across this disease so I further researched the subject.

What is Kawasaki Disease?

Kawasaki Disease, otherwise known as Mucocutaneous Lymph Node Syndrome, is a rare condition that occurs in children. This disorder involves inflammation of the blood vessel walls and can also involve the mucus membranes, lymph nodes, and the heart. The disease can be completely cured if treated promptly, however, if treatment is delayed, complications involving the heart can be very serious. If untreated, inflammation of the blood vessels in the coronary arteries can occur, which can lead to aneurysms, which can possibly lead to a heart attack.

Some facts about Kawasaki Disease:

This condition was first discovered in Japan, where it most frequently occurs, but can occur in all ethnicities. In the United States, over 4,000 children develop this condition each year, and it is the leading cause of acquired heart disease in children. Most children who are struck with this disease are under age 2, and 80% of all cases occur in children age 5 and under. The cause of this disease is unknown; however, there is speculation that it may be an autoimmune disorder that is triggered by outside factors.

Signs and Symptoms

Often the first sign of the disease is a high fever (greater than 102°F) that lasts at least 5 days and is not very responsive to acetaminophen or ibuprofen. Other symptoms that can occur are:
- bloodshot or red eyes (without pus or drainage)
- bright red, chapped/cracked lips
- red mucous membranes of the mouth
- strawberry tongue, white coating on the tongue, or red bumps on the back of the tongue
- red palms of the hands and soles of the feet
- swollen hands and feet
- skin rashes on the trunk (NOT blister like)
- peeling skin in the genital area, hands and feet
- swollen lymph nodes (usually unilateral, in the neck area)
- joint pain and swelling (usually bilateral)

Diagnostic Tests

There are no specific tests that can diagnose Kawasaki disease. The diagnosis is usually made based on the patient's presentation of fever and at least 4 of the other classic symptoms. (Atypical Kawasaki disease, which can also occur, involves fewer than 4 of the principal features.) Because of the increasing reports of atypical disease, all children who present with a fever lasting longer than 5 days should be evaluated for the disease. The tests that can be performed to confirm the disease are:
- CBC
- ESR
- Electrocardiogram
- Echocardiogram
- Chest X-ray
- Urinalysis

Treatment

Gamma Globulin

The use of IVIG can shorten the acute phase of the disease and prevent any damage to the heart. After the fever has subsided for at least 2-3 days, the dose of IVIG can be decreased. If after 10 days from diagnosis, the child still has a fever, IVIG may still be useful, but the patient will need to be carefully monitored since children react differently to this medication.

Aspirin

Aspirin is used to decrease inflammation, lower the fever, and prevent blood clots from developing. It has never been shown to decrease the risk of aneurysms.

High dose aspirin are used in the first few days to control the fever, and once it has subsided for 2-3 days, the dose is decreased. Low dose aspirin is continued during the recovery phase and then stopped.

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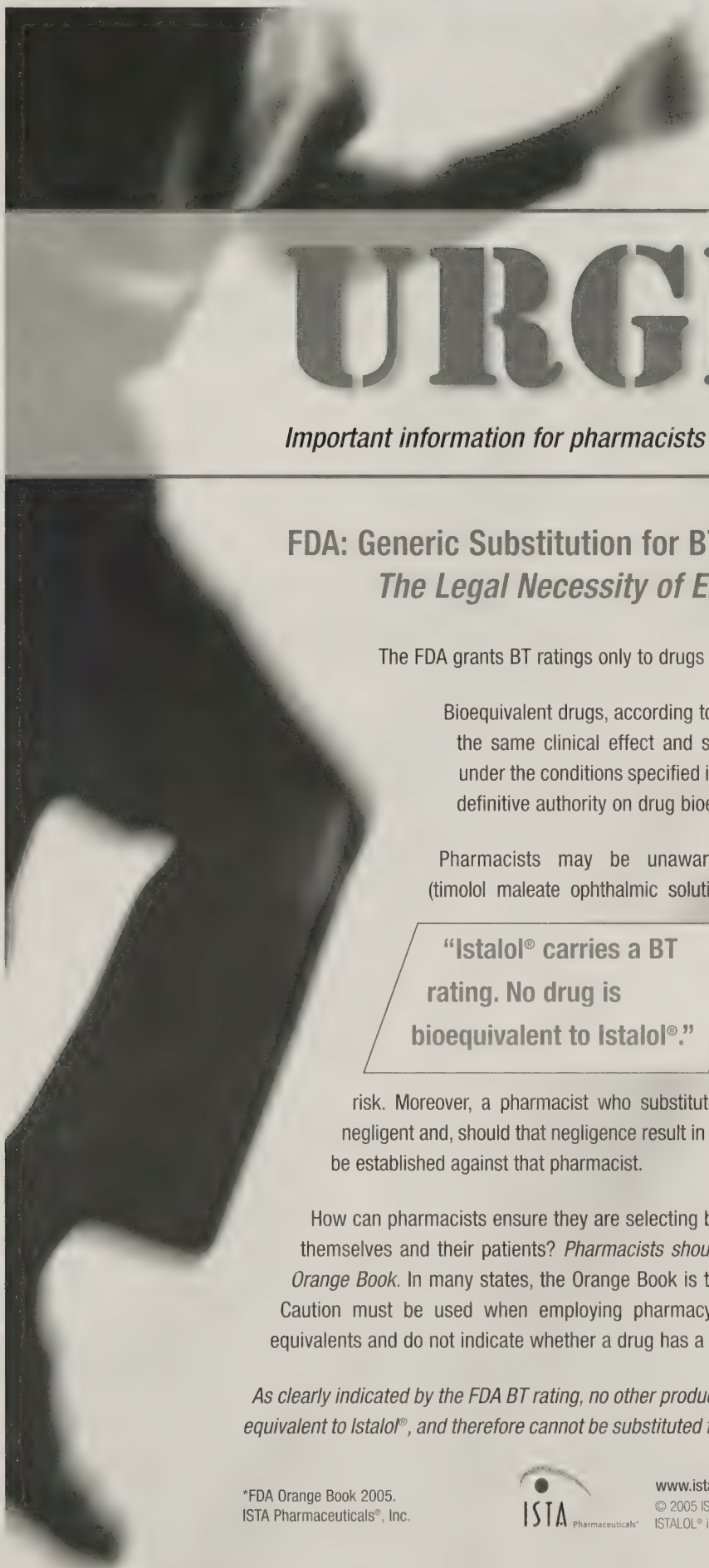

URGENT

Important information for pharmacists treating patients with glaucoma

FDA: Generic Substitution for BT-Rated Meds Carries Risk

The Legal Necessity of Ensuring Bioequivalence

The FDA grants BT ratings only to drugs with no recognized bioequivalent.

Bioequivalent drugs, according to the Orange Book, "can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." The Orange Book remains the definitive authority on drug bioequivalence.

Pharmacists may be unaware that ophthalmic beta-blocker Istalol® (timolol maleate ophthalmic solution) 0.5% carries a BT rating.* No drug is bioequivalent to Istalol®. *It may be illegal in your state to substitute BT-rated products.* Check pharmacy laws in your state. Such substitutions have the potential to place a pharmacist's professional license and personal assets at risk. Moreover, a pharmacist who substitutes a drug that is not bioequivalent may be negligent and, should that negligence result in injury to a patient, a legal cause of action may be established against that pharmacist.

"Istalol® carries a BT rating. No drug is bioequivalent to Istalol®."

How can pharmacists ensure they are selecting bioequivalent medications, thereby protecting themselves and their patients? *Pharmacists should refer to the FDA authoritative source, the Orange Book.* In many states, the Orange Book is the only official reference for bioequivalence. Caution must be used when employing pharmacy software programs that only list generic equivalents and do not indicate whether a drug has a BT rating.

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Continuing Education for Pharmacists

Volume XXII, No. 4

Management of Erectile Dysfunction: Focus on Levitra and Cialis

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

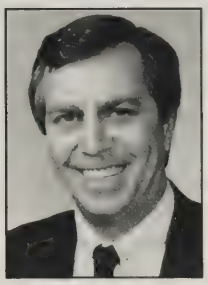
Goals. The goals of this lesson are to provide background information on erectile dysfunction and review the newest drugs, Levitra (vardenafil) and Cialis (tadalafil), approved for its treatment.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. explain the etiology and incidence of erectile dysfunction;
2. identify factors associated with its onset;
3. identify the pharmacologic classification and therapeutic considerations for the drugs discussed; and
4. select from a list, the indications, mechanism of action, adverse effects and toxicities, drug interactions, and benefits and limitations of the drugs presented.

Once a taboo topic for public discussion, the subject of erectile dysfunction (ED) is now commonplace. With two new drugs, Levitra (vardenafil) and Cialis (tadalafil),

Gossel



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approved in 2003 to treat ED, pharmacists are likely to be included in these discussions. Erectile dysfunction is the most common male sexual dysfunction, and the leading complaint of males attending sex therapy clinics.

Anatomy of the Human Penis

The penis is a highly vascular organ that consists of two parallel cylinders of erectile tissue located throughout the length of the penile shaft, the corpus cavernosum. A smaller cylinder, the corpus spongiosum, surrounds the urethra to form the glans penis at its terminus.

Blood supply into the penile tissues is provided by the paired cavernosal branches of the internal pudendal artery that divides into numerous terminal branches that open directly into the cavernous spaces.

Both autonomic and somatic nerves innervate the penis. Sympathetic and parasympathetic fibers of the autonomic system join in the pelvis to form the cavernous nerves that innervate the corpus cavernosum, corpus spongiosum, and glans penis to regulate blood flow during erection and detumescence (subsidence of swelling; i.e., moving toward flaccidity). Somatic fibers (the pudendal nerve) are responsible for penile sensation, and contraction and relaxation of the extracorporeal striated muscles.

Physiology of Erection

Penile erection requires a number of complex neuropsychological, hormone-mediated, and vascular interactions. When the penis is flaccid, blood flow into and out of the erectile bodies is in balance. Sympathetic activity via alpha-2-adrenergic receptors maintains contraction of both the penile arterial and cavernosal smooth muscles, which preserves high penile arterial resistance and flaccidity.

Upon arousal, parasympathetic activity initiates a series of biochemical actions beginning with increased formation and liberation of nitric oxide (NO), vasoactive polypeptide, and prostaglandin E_1. Nitric oxide, originally referred to as endothelium-derived relaxing factor, is a potent vasodilator released from endothelial cells that line blood vessels. Nitric oxide is believed to be the most important neurotransmitter in the erectile process. Its action promotes formation of cyclic guanosine monophosphate (cGMP), which in turn depletes intracellular calcium that leads to smooth muscle relaxation with erection.

Neuronal activity decreases following orgasm. The enzyme phosphodiesterase-5 (PDE-5) breaks down cGMP. Nitric oxide release is terminated and generation of cGMP within the cells ceases. By reducing intracellular levels of cGMP, PDE-5 therefore, inhibits vasodilation of the penile vasculature. Detumescence begins. Blood flow into the penis returns to baseline, and blood drains from the erectile tissues because the venous plexus of the

penis is no longer compressed. Erection is lost and the penis returns to its flaccid state.

Erectile Dysfunction

Erectile dysfunction is defined as the persistent inability to attain or maintain penile erection adequate for sexual intercourse. The term replaces the older descriptor *impotence* since the latter term often led to confusing and uninterpretable results in both clinical and basic science investigations. ED is a symptom complex which is frequently multifactorial in etiology.

Erectile dysfunction affects an estimated 152 million men worldwide, with 25 million or more in the U.S. There is a higher prevalence of complete ED in men with concomitant illnesses.

Psychogenic vs. Organic Origin. Erectile dysfunction can be classed broadly into two categories by etiology: psychogenic (functional) and organic (physical). Evidence suggests that approximately 80 percent of cases are organic in nature, caused by physiological conditions, including cardiovascular disease and diabetes mellitus. Both psychogenic and organic factors may contribute to the condition. For example, after experiencing a myocardial infarction, patients may be apprehensive about performing sexual activity. In this case, cardiovascular disease (i.e., organic cause) initiated the ED which was worsened by apprehension (i.e., psychogenic cause).

Psychogenic ED (e.g., "performance anxiety") is usually episodic. The classical presentation is described by ED of sudden onset, often preceded by extreme stress.

Erectile dysfunction of organic origin is characterized by gradual onset of deterioration of rigidity and decreased frequency of erection. Men may no longer be able to achieve erection through fantasizing or masturbation. Attempts at intercourse are often unsuccessful during periods of fatigue or stress. Libido is often normal, but diminishes with any kind of ED.

Organic causes may be of vascular, neurologic or hormonal etiology. Vascular causes are most common with disorders of the arterial vasculature supply rather than venous outflow being at cause. Regardless, a psychogenic component frequently coexists to compound accurate diagnosis and assessment of the patient's condition. Descriptors including mild, moderate, or complete are often applied to ED, even though they are highly subjective and cannot be defined precisely.

Conditions Associated with Erectile Dysfunction

Conditions (i.e., risk factors) associated with ED are summarized broadly in Table 1. Aging is the most important independent factor. Young men are often capable of achieving erection within seconds simply by fantasizing. By age 40 or 50, this becomes increasingly difficult. Although the incidence of ED increases steadily with age, ED should not be considered an inevitable consequence of growing older. Many men well into their 80s and beyond report experiencing rigid erections and a healthy sex life.

Smoking almost doubles the probability of developing moderate to complete ED. Chronic alcoholism may affect erectile ability adversely through altered hormone metabolism and polyneuropathy. Medical disorders associated with ED include those that impair arterial blood supply to the erectile tissues or disrupt the neuronal circuitry. Patients with diabetes mellitus and/or cardiovascular disease, for example, experience high rates of ED.

Drugs that interfere with central neuroendocrine or local neurovascular control of penile smooth muscle have the potential to cause iatrogenic (i.e., treatment-related) ED (Table 2). The precise mechanism(s) for this adverse action for most causative agents is unknown even for those drugs reported to cause ED to greatest extent.

Table 1
Conditions Associated With Erectile Dysfunction

Aging/Lifestyle
cigarette smoking
chronic alcohol abuse
drug abuse
Chronic Disease
diabetes mellitus
heart disease
hypertension
lipid disorders/atherosclerosis
renal failure
liver disease
sickle cell anemia
idiopathic hemochromatosis
chronic obstructive pulmonary disease
leukemia
scleroderma
Endocrine Abnormalities
hypogonadism
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depression
widower's syndrome
anxiety
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Trauma/Injury
pelvic or perineal trauma/surgery
pelvic radiation
prostate surgery
Nutritional
protein malnutrition
zinc deficiency
Infection
AIDS
brucellosis
trypanosomiasis
tuberculosis
Drugs
see table 2

Vardenafil and Tadalafil

Levitra (vardenafil) and Cialis (tadalafil), like Viagra (sildenafil),

are selective inhibitors of PDE-5 which inactivates cGMP. With release of NO into the penile smooth muscle following sexual stimulation, inhibiting PDE-5 enhances the activity of cGMP concentrations in the glans penis, corpus cavernosum, and corpus spongiosum. This promotes NO-induced smooth muscle relaxation, engorgement with blood, and firm erection. Because sexual stimulation is required to initiate the local release of NO, the inhibition of PDE-5 has no effect in the absence of sexual stimulation.

Clinical Trials. In one clinical trial with vardenafil, 762 men (mean age 57, range 20-83 years) were evaluated. There was significant improvement at three months with the drug improving the rates of achieving an erection sufficient for penetration at doses of 5 mg, 10 mg, and 20 mg (65 percent, 75 percent, and 80 percent, respectively) vs. 52 percent response for placebo. Men taking vardenafil were able to achieve and maintain an erection sufficient to complete successful intercourse (51 percent on 5 mg, 64 percent on 10 mg, and 65 percent on 20 mg doses, respectively, compared to 32 percent with placebo).

Several studies were conducted with tadalafil with the objective of determining the optimal use of tadalafil in the treatment of ED. In one clinical study, the percentage of patients achieving successful erections within 30 minutes of dosing was determined. Two hundred twenty-three patients were randomized to tadalafil 10 mg or 20 mg, or to placebo. Using a stopwatch, patients recorded the time following dosing at which a successful erection was obtained. A successful erection was defined as at least one erection in four attempts that led to successful intercourse. At or prior to 30 minutes, 38 percent and 52 percent of patients in the tadalafil 10 mg and 20 mg groups, vs. 35 percent of patients with placebo, reported successful erections as defined above.

Adverse Effects. Vardenafil was administered to over 4430 men (mean age 56, range 18-89 years) during controlled and uncontrolled clinical trials worldwide. More than 2200 men received the drug for six months or longer, and 880 patients were treated for at least one year. When vardenafil was taken as recommended, the following adverse events were reported by >2 percent of patients treated with the drug and more frequently on drug than placebo: headache, flushing, rhinitis, dyspepsia, sinusitis, flu syndrome, dizziness, increased creatine kinase, and nausea. The discontinuation rate due to adverse events was 3.4 percent for vardenafil compared to 1.1 percent for placebo.

Tadalafil was administered to over 5700 men (mean age 59, range 19-87 years) during clinical trials worldwide. Over 1000 received the drug for a year or longer; over 1300 were treated for >six months. When tadalafil was taken as recommended, the following adverse events were reported in >2 percent of patients treated with 10 or 20 mg tadalafil and more frequently on drug than placebo: headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and limb pain. In Phase 3 clinical trials, the discontinuation rate due to adverse effects in patients treated with tadalafil was 3.1 percent, compared to 1.4 percent in placebo-treated patients.

Rare events of erections greater than four hours and priapism (painful erections lasting longer than six hours) are reported for PDE-5 inhibitors, including Levitra and Cialis. The patient should seek immediate medical assistance in the event that an erection persists longer than four hours. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

Phosphodiesterase inhibitors have caused rare instances of dose-related changes in color discrimination such as seeing a blue tinge or having difficulty differentiating between blue and green. A single study involving 25 men who received 40 mg doses of Levitra, and a single study involving 59 men who received 40 mg doses of Cialis, failed to show altered visual acuity.

Table 2
Representative Drugs Associated with Erectile Dysfunction

Diuretics
thiazides
spironolactone
Antihypertensives
methyldopa
clonidine
reserpine
beta-adrenergic blockers
guanethidine
verapamil
Cardiac
clofibrate
gemfibrozil
digoxin
Tranquilizers
phenothiazines
butyrophenones
barbiturates
Antidepressants
tricyclic antidepressants and other antidepressants
MAO inhibitors
lithium
H_2-receptor antagonists
cimetidine
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Hormones
estrogens
progesterone
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Cytotoxic Agents
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baclofen
carbonic anhydrase inhibitors
NSAIDs
amphetamines
opiates
finasteride

Drug Interactions. Administration of Levitra or Cialis with nitrates (dosed regularly and/or intermittently) is contraindicated.

Phosphodiesterase inhibitors may potentiate their hypotensive effects including rapid heart rate.

The drugs are also contraindicated in patients taking alpha-adrenergic receptor antagonists since co-administration can produce hypotension. There is a single exception – administration of Cialis (but not Levitra) is approved for concomitant administration in patients taking 0.4 mg once-daily doses of tamsulosin (Flomax).

Ritonavir (Norvir) and indinavir (Crixivan) – both strong inhibitors of CYP3A4 – increase plasma concentrations of Levitra. To reduce the chance of an adverse reaction in patients taking Norvir or Crixivan, a maximum single dose of 2.5 mg Levitra should not be exceeded. Dosing should be limited to a single 2.5 mg dose of Levitra taken in a 72-hour period by patients also taking Norvir. Men taking Crixivan, ketoconazole 400 mg daily, or itraconazole (Sporanox) 400 mg daily should not exceed doses of Levitra greater than 2.5 mg once daily. For patients taking erythromycin, ketoconazole or itraconazole 200 mg daily, a single dose of 5 mg Levitra should not be exceeded in a 24-hour period.

Ketoconazole (400 mg daily) increases Cialis 20-mg single-dose exposure (AUC) by 312 percent and C_{max} by 22 percent, compared to the values for Cialis 20 mg alone. Norvir (200 mg twice daily) increases Cialis 20 mg single-dose exposure (AUC) by 124 percent with no change in C_{max}, compared to the values for Cialis 20 mg alone. Based upon these results, in patients taking concomitant potent CYP3A4 inhibitors, the dose of Cialis should not exceed 10 mg, and should not be taken more frequently than once every 72 hours.

Dosage and Administration. The recommended starting dose of Levitra for most patients is 10 mg, taken orally approximately 60 minutes before sexual activity. The usual dosage spans the range of 5 mg to 20 mg based on efficacy and side effects. A lower dose, 2.5 mg, may be appropriate for patients taking other drugs that interact with Levitra. A starting dose of 5 mg Levitra is recommended for patients >65 years of age. The recommended dosing frequency is one dose per day. Levitra can be taken with or without food.

No dose adjustment is required for patients with mild hepatic impairment. A starting dose of 5 mg is recommended for patients with moderate hepatic impairment, with maximum dose up to 10 mg. Levitra has not been evaluated in patients with severe hepatic impairment. No dose adjustment is required for patients with mild, moderate, or severe renal impairment. Levitra has not been evaluated in patients on renal dialysis.

The cardiovascular status of patients should be assessed before starting on Levitra. It is not recommended for men who have suffered a myocardial infarction or stroke within the past six months, or persons with significant hypotension or uncontrolled hypertension, unstable angina, severe liver impairment, end-stage renal disease requiring dialysis, or retinitis pigmentosa, a hereditary, degenerative retinal disorder. The drug should be used cautiously in patients with anatomical deformity of the penis, such as Peyronie's disease, and men predisposed to priapism, such as in sickle cell anemia, multiple myeloma, or leukemia.

Levitra is available as orange, film-coated round tablets containing 2.5, 5, 10, or 20 mg vardenafil.

The recommended initial dose of Cialis in most patients is 10 mg, taken prior to anticipated sexual activity. The dose may be increased to 20 mg or decreased to 5 mg, based on individual efficacy and tolerability. The maximum recommended dosing frequency is once per day in most patients, taken without regard to food. While the FDA-approved dosage does not address when to take Cialis, the manufacturer's patient information leaflet states that in some men, improved sexual activity was apparent 30 minutes after taking a dose with erectile function improved up to 36 hours following dosing, compared to placebo.

For patients with mild or moderate hepatic impairment, the dose of Cialis should not exceed 10 mg once daily. The drug is not recommended in patients with severe hepatic impairment. No dose adjustment is required in patients with mild renal insufficiency. For patients with moderate renal insufficiency, a starting dose of 5 mg, not more than once daily, is recommended, and the maximum dose should be limited to 10 mg, not more than once every 48 hours. A maximum dose of 5 mg is recommended for patients with severe renal insufficiency on hemodialysis.

Until further information is available, Cialis is not recommended in patients with a myocardial infarction within the last 90 days, or patients with unstable angina or angina occurring during sexual intercourse. It is not recommended in persons with stroke or Class 2 or greater heart failure in the last six months, or patients with uncontrolled arrhythmias, hypotension, or uncontrolled hypertension. In addition, it is not recommended in patients with known hereditary degenerative retinal disorders, including retinitis pigmentosa.

Cialis is supplied as yellow, film-coated almond-shaped tablets containing 5, 10, or 20 mg tadalafil.

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Continuing Education Quiz

This month's questions are taken from the article on "Management of Erectile Dysfunction: Focus on Levitra and Cialis". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 4/15/07. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-04-004-H01.

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1. Sympathetic and parasympathetic fibers of the autonomic nervous system join in the pelvis to form the:
   a. erectile nerves.
   b. perineal nerves.
   c. cavernous nerves.
   d. pelvic nerves.

2. High penile arterial resistance and flaccidity are preserved by the sympathetic activity via:
   a. alpha-2-adrenergic receptors.
   b. beta-1-adrenergic receptors.
   c. beta-2-adrenergic receptors.
   d. serotonin-5HT-1 receptors.

3. The most important neurotransmitter in the erectile process is believed to be:
   a. adrenalin.
   b. nitric oxide.
   c. testosterone.
   d. norepinephrine.

4. The enzyme that breaks down cGMP is:
   a. testosterone reductase.
   b. cytochrome oxidase.
   c. angiotensin converting enzyme.
   d. phosphodiesterase.

5. All of the following are organic causes of erectile dysfunction EXCEPT:
   a. hormonal.
   b. neurologic.
   c. psychogenic.
   d. vascular.

6. The most important independent risk factor for erectile dysfunction is:
   a. aging.
   b. cardiovascular disease.
   c. diabetes.
   d. enlarged prostate.

7. Painful erections lasting longer than six hours are referred to as:
   a. precocity.
   b. priapism.
   c. hypergonadism.
   d. impotency.

8. Concurrent administration of Levitra and Cialis is contraindicated with which of the following groups of drugs?
   a. Androgens
   b. Cytochrome P450 oxidase inhibitors
   c. Monoamine oxidase inhibitors
   d. Nitrates

9. The recommended starting dose for Levitra for most patients is:
   a. 2.5 mg.
   b. 10 mg.
   c. 25 mg.
   d. 100 mg.

10. Which of the following is claimed to improve sexual activity 30 minutes after taking the dose, with erectile dysfunction improved up to 36 hours?
   a. Cialis
   b. Levitra
   c. Viagra
   d. Yohimbine

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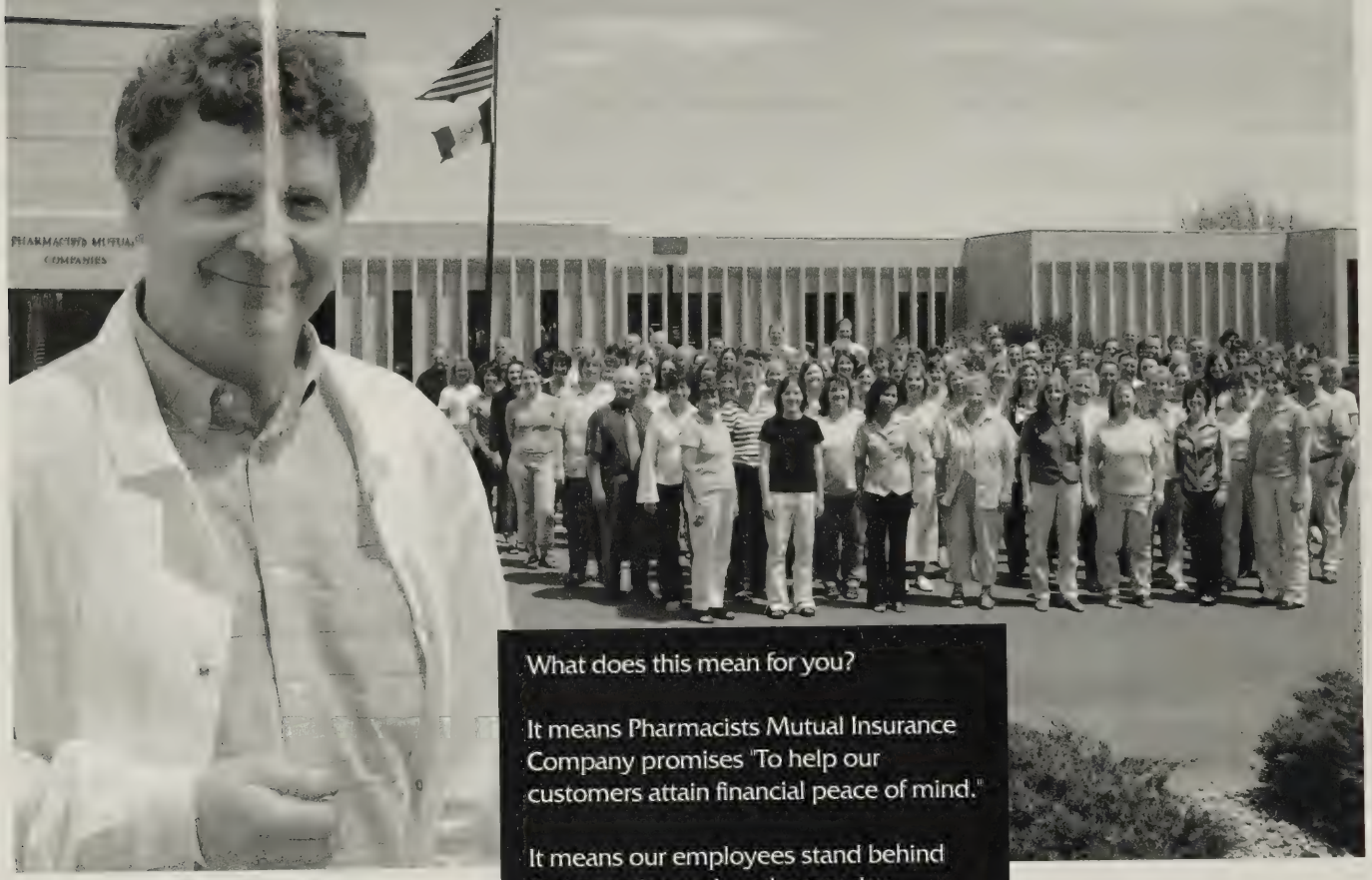

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P.O. Box 177
Kingsville, MD 21087
410-592-9856
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